In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-934V

Filed: September 4, 2019

MICHELLE DIXON-JONES,	*	PUBLISHED
Petitioner,	*	
v.	*	Dismissal; Influenza Vaccine; Chronic Regional Pain Syndrome; Small Fiber Neuropathy; Insufficient Proof of Causation
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amber D. Wilson, Maglio Christopher & Toale, Law Firm, Washington, DC, for Petitioner.
Sarah C. Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

Oler, Special Master:

On October 3, 2014, Michelle Dixon-Jones ("Ms. Dixon-Jones" or "Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10.[2] ("Vaccine Act" or "the Program"). In her petition Ms. Dixon-Jones alleges that the influenza ("flu") vaccination she received on October 6, 2011, caused her to suffer from right arm swelling, extreme pain in the left ear, swelling of both hands, facial rash and shortness of breath, right eye twitching, vertigo, nausea, short term memory loss, and worsening of her fibromyalgia.[3] *See*

[1] This decision will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided in 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, each party may, within 14 days, request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, this decision will be available to the public in its present form. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Although Petitioner alleges worsening of fibromyalgia in the petition, Petitioner's expert, Dr. Aradillas, testified at hearing that Petitioner did not have fibromyalgia. Tr. at 107. As a result, I have not analyzed whether Petitioner's flu vaccination caused a significant aggravation of her fibromyalgia.

Petition ("Pet."), ECF No. 1. Although no specific diagnosis was alleged in the petition, Petitioner's expert, Dr. Enrique Aradillas-López ("Dr. Aradillas") diagnosed Ms. Dixon-Jones with Chronic Regional Pain Syndrome ("CRPS") and Small Fiber Neuropathy ("SFN") following the receipt of her flu vaccination on October 6, 2011. Ex. 37 at 2.

Upon review of the evidence submitted in this case, I find that Petitioner has failed to carry her burden showing that she is entitled to compensation under the Vaccine Act. Petitioner has failed to show that she suffered from CRPS or SFN or that the flu vaccination she received caused any of her symptoms. The petition is accordingly dismissed.

I. Procedural History

Petitioner filed her petition on October 3, 2014.[4] ECF No. 1. On June 9, 2015, Respondent filed a Rule 4(c) Report, presenting his analysis of Petitioner's claims and concluding that entitlement should be denied in this case. ECF No. 18. Petitioner filed Dr. Aradillas' expert report on January 22, 2016 along with Dr. Aradillas' curriculum vitae ("CV"). ECF No. 26, filed as Exhibits ("Ex.") 37, 38. Petitioner submitted medical literature on February 1, 2016. ECF Nos. 27-30. Respondent filed a responsive expert report of Dr. Phillip A. Low, as well as Dr. Low's CV, on April 22, 2016. ECF No. 33, filed as Exs. A, B. An entitlement hearing was scheduled for January 29, 2018. ECF No. 42.

At Petitioner's request (ECF No. 50), I held a Rule 5 Status Conference on December 19, 2017, ultimately instructing the parties to ensure that their respective experts were prepared to answer at hearing the questions I posed during the conference. ECF No. 51. On January 3, 2018, I granted the parties an extension of time to file their respective pre-hearing submissions by January 12, 2018. The parties filed their pre-hearing submissions on January 12, 2018, and Petitioner timely filed medical literature (Exs. 74-116) on January 15, 2018. ECF Nos. 55-59. The parties filed their joint pre-hearing submission on January 16, 2018. ECF No. 60.

I issued a supplemental pre-hearing order on January 19, 2018, discussing a disciplinary proceeding against one of Petitioner's treating physicians, Dr. Walter E. Kozachuk. ECF No. 61. The Maryland State Board of Physicians charged Dr. Kozachuk with "unprofessional conduct in the practice of medicine and failing to meet the appropriate standards for the delivery of quality medical care." An Administrative Law Judge upheld the Board's charges, finding that Dr. Kozachuk met with several patients and wrote prescriptions for oxycodone, Xanax, and penicillin in exchange for cash at Daniels Restaurant and Bar in Elkridge, Maryland and G.L. Shacks Grill in Catonsville, Maryland. https://www.mbp.state.md.us/bpqapp/Orders/D3727904.256.PDF (last visited August 27, 2019).[5]

Petitioner filed an amended petition and medical records on January 19, 2018. ECF Nos.

[4] This case was initially assigned to now-retired Special Master Hastings (ECF No. 4), reassigned to Special Master Corcoran on October 4, 2017 (ECF No. 45), and then reassigned to my docket on November 29, 2017 (ECF No. 48).

[5] The decision of the Administrative Law Judge was upheld by the Court of Appeals of Maryland. *Kozachuk v. Maryland State Board of Physicians* (Dec. 13, 2017).

63-65. On January 22, 2018, I held a status conference, and the parties discussed the additional records that Petitioner filed (i.e., medical literature (Exs. 74-116), amended petition, and medical records (Exs. 117-127)). ECF No. 67. In light of the volume of records that were submitted by Petitioner, Respondent requested that the hearing date be rescheduled; Petitioner had no objection. *Id*. I rescheduled the entitlement hearing for July 23, 2018. ECF No. 69. Petitioner filed additional medical records and a supplemental brief on June 22, 2018 (ECF No. 70, 71), and on July 2, 2018, Petitioner filed additional medical records (ECF No. 72). Petitioner filed a supplemental affidavit on July 6, 2018. ECF No. 73.

I held an entitlement hearing on July 23, 2018 and ordered the parties to submit additional documents to supplement the record. ECF No. 75. Respondent filed medical literature on July 31, 2018. ECF No. 76, filed as Ex. K. The Transcript of Proceedings ("Tr.") was entered on August 15, 2018. Petitioner filed medical literature on August 24, 2018. ECF No. 79. I held a status conference on September 6, 2018, setting a deadline for the parties to submit their respective post-hearing briefs. ECF No. 81. During the status conference, Petitioner's counsel represented that Petitioner will not pursue SFN as a claim in this case.[6] *Id*. The parties filed their post-hearing briefs on December 5 and 6, 2018. ECF No. 83, 84. In accordance with her counsel's representation during our status conference that she would not pursue a theory that the flu vaccine caused SFN, Petitioner's post-hearing brief did not mention SFN. Both sides indicated the record was complete on February 22, 2019. ECF No. 86. Accordingly, this matter is now ripe for adjudication.

II. Factual Background

A. Petitioner's Health Prior to the Allegedly Causal Vaccination

Ms. Dixon-Jones' pre-vaccination medical history is quite significant. In 1999, she was in a motor vehicle accident and suffered a blunt head injury. Ex. 24 at 16, 19. She was subsequently diagnosed with bilateral carpal tunnel syndrome and right brachial plexopathy. *Id*. She has asthma, which has been treated with Advair since 2000. *Id.* at 3. She has hypothyroidism, which has been treated with Synthroid since 2002. *Id*. In 2004, she had abdominal pain and evidence of pancreatitis. Ex. 12 at 11. She was later diagnosed with pancreatitis in 2011. *Id*. at 10.

On March 10, 1999, Ms. Dixon-Jones was admitted to the hospital due to a motor vehicle accident that occurred the day before. Ex. 10 at 81. The location of her injuries was noted to be the neck and right shoulder. *Id*.

On January 4, 2000, she was seen at Howard County General Hospital for neck pain. Ex. 10 at 73. Her pain had been intermittent since March of 1999 and was noted to be worse. *Id*. She was noted to have a headache. *Id*. The severity of her pain was described as radiating and neurologic symptoms revealed "radiation to arm." *Id*. Her pain was exacerbated by nothing and

[6] I specifically asked Ms. Wilson whether Petitioner still planned to pursue her SFN claim after Dr. Aradillas testified at hearing that he had a low degree of confidence the flu vaccine caused Petitioner to develop SFN. Based on Ms. Wilson's representation, I have not analyzed the claim of SFN raised in the petition.

relieved by nothing. *Id*. She had decreased range of motion and muscle spasm. *Id*. at 74. Her primary diagnoses were neck pain and radiculopathy. *Id*.

Ms. Dixon-Jones had a right radial sensory nerve compression of the forearm on July 14, 2000, due to the pain she had in her right forearm along the dorsal radial. Ex. 15 at 16. She had a right carpal tunnel release on April 19, 2001. *Id*. at 70. She had a left carpal tunnel release on May 24, 2001. *Id*. at 46.

Petitioner had a workman's compensation injury involving her neck, back, left arm, and left leg on August 21, 2002, when her chair collapsed while she was at work. Ex. 25 at 48. In light of her injury, she "had multiple surgeries" and has "chronic pain." *Id*.

On October 15, 2003, Petitioner had an esophagogastroduodenoscopy[7] with biopsy due to recurrent reflux symptoms that included heartburn, bitter saliva, dysphagia, and chest discomfort. Ex. 10 at 96. The diagnosis was reflux esophagitis that was moderate to severe. *Id*.

On December 9, 2005, Ms. Dixon-Jones had an MRI of the thoracic spine. Ex. 123 at 49. The MRI revealed "a moderate, broad-based, left paracentral soft disc herniation at T8-9." *Id*. She also had a MRI of the lumbosacral spine, which revealed a "[s]mall focal central soft disc herniation slightly more to the right side, at L5-S1," and the physician noted that such a "finding has to be correlated clinically." *Id*. at 50. "She reported tenderness to palpation of the muscles of her neck, shoulders and arms. She had slight reduction in her strength…." *Id*.

On June 15, 2006, Ms. Dixon-Jones had a nerve conduction study/electromyography. Ex. 18 at 29. The record acknowledges her "long history of upper extremity pain[, which she] attributes the initial onset of the pain to a motor vehicle accident….Despite receiving bilateral carpel tunnel syndrome surgery as well as neurolysis of her right radial nerve, she continued to have pain." *Id*. The record notes that her symptoms were "somewhat dormant[,] but have never resolved." *Id*. The pain in her arms increased since her diagnosis of pancreatitis the prior year. *Id*.

In 2006, she was diagnosed with lumbar disc degeneration with an abnormal MRI, and she had radicular pain that was treated with epidural injections. Ex. 24 at 3.

She had a gastroenterology consultation on May 15, 2008 due to abdominal pain. Ex. 19 at 7. She was taking an increased dosage of Advil for her back aches and had experienced, for the past 10 to 12 days, severe left upper quadrant and epigastric pain. *Id*. Her pain felt like cramps "with little radiation to the back" and was "accompanied with nausea but no vomiting or heartburn." *Id*. She denied dysphagia. *Id*. Physical examination revealed epigastric and left upper quadrant tenderness. *Id*. at 8.

On May 29, 2008, she had a follow up visit with Dr. Hanif for abdominal pain. The record notes that the pain and burning in her left upper quadrant was "more prominent in the morning and

[7] An endoscopic examination of the esophagus, stomach, and duodenum. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) at 648 (hereinafter "Dorland's").

persists through the daytime." Ex. 19 at 5. Physical examination of her abdomen noted that it was soft and non-tender. *Id*. at 6. Dr. Hanif's impression was chronic gastritis and irritable bowel syndrome (IBS). *Id*.

On October 4, 2009, Ms. Dixon-Jones had an MRI of the thoracic spine, which revealed "a degenerating disk in the midthoracic spine with mild posterior protrusion" and there were "some osteoarthritic changes of the thoracic facets." Ex. 125 at 209. Her medical record notes that sometime in 2009, she had an H1N1 infection and encephalitis. Ex. 25 at 40. "Thereafter she started with episodes of dizziness and recurrent syncope." *Id*.

Ms. Dixon-Jones saw Dr. Ogunsola on October 16, 2009 for mid and low back pain. Ex. 13 at 32. He reported that her pain was ongoing for several years and that it was worsening. *Id*. She had occasional burning in the mid back area, which radiated laterally on the right side. *Id*. She also had an achy sensation in her low back, which radiated into her right buttock and right thigh. *Id*. The pain questionnaire showed that the location of her pain was in her back. *Id*. at 38. The questionnaire included a diagram of the front-side and back-side of the human body, and the back was shaded to reflect that the area of pain was in her back. *Id*. Her pain was described as intermittent, worsening with prolonged sitting, cold temperature, certain weather, and emotional stress. *Id*. at 39.

Between March 24 and 31, 2010, Ms. Dixon-Jones was admitted at Northwest Hospital Center due to abdominal pain that started two days earlier. Ex. 11 at 214-15. Onset of her abdominal pain was abrupt, and it became progressively worse. *Id*. at 215. The record notes that the course was constant and that she "mainly felt pain in the left flank area." *Id*. Ms. Dixon-Jones was also nauseated and vomiting and had mild epigastric pain. *Id*. Physical examination of her abdomen revealed "presence of epigastric and left flank tenderness," and she did not have "right upper extremity tenderness." *Id*. at 215-16. Two gallstones were found in her gallbladder and uterine fibroids were found in her pelvis. *Id*. at 216. She had a consultation for her "persistent nausea, abdominal and back pain for a month, which became worse." *Id*. at 218. History of present illness ("HPI") noted that she was "in the usual state of her health until a month ago when she started to have persistent nausea, abdominal and back pain." Her abdominal pain was severe, cramping in nature, and it radiated to her back and was accompanied by nausea. *Id*. Milk of magnesia eased her constipation. *Id*. The discharge summary discusses the procedures that Ms. Dixon-Jones underwent while admitted. *See id*. at 204; *see also id*. at 212-13 (Petitioner had an operation to have her gallbladder removed).

B. Petitioner's Health after the Allegedly Causal Vaccination

Ms. Dixon-Jones received an inactivated flu vaccine in her right deltoid on Thursday, October 6, 2011, at her place of employment, Saint Agnes Hospital. Ex. 1.

On October 12, 2011, Ms. Dixon-Jones saw Dr. Michael Mardiney, Jr. at Mardiney Asthma, Allergy & Immunology Center ("AAIC"), reporting that she experienced pain and swelling in her right arm about two and one half hours after her flu vaccination. She further reported that the following Friday morning, around 3:30 AM, she experienced "extreme pain in [her] left ear, swelling of both [of her] hands, facial rash[,] and shortness of breath." Ex. 26 at 27.

Physical examination revealed that Ms. Dixon-Jones had clear skin, no hives, and no angioedema. *Id*. Ms. Dixon-Jones reported tightness of her chest. *Id*. The injection site of her flu vaccination was not visible. *Id*. It was the doctor's impression that Ms. Dixon-Jones had an "adverse response to [the] flu vaccine, manifested by angioedema, as well as bronchospasm[.]" *Id*. The doctor also assessed Petitioner with Eustachian tube dysfunction and skin rash. *Id*. A Vaccine Adverse Event Reporting System ("VAERS") form was completed on October 14, 2011, detailing Ms. Dixon-Jones' onset of symptoms. Ex. 26 at 25. In addition to the symptoms reported to Dr. Mardiney on October 12, 2011 and his impressions, the VAERS report states that Ms. Dixon-Jones had a rash on her face on October 7, 2011, and that it was her first time receiving flu vaccine. *Id*.

On October 23, 2011, Ms. Dixon-Jones visited Northwest Hospital Center for abdominal pain, reporting that she had been experiencing such pain since receiving her flu vaccine. Ex. 11 at 8. Her complaint of epigastric pain was described as a moderate burning sensation, and she used a laxative to induce bowel movement since she was unable to produce bowel movement for the past seven days. *Id*. Although she mentioned experiencing nausea, she denied vomiting. *Id*. She rated her chest pressure a three out of ten, and she was no longer experiencing shortness of breath. *Id*. Her diagnoses were abdominal pain and chronic pancreatitis, and it was noted that she had a follow-up visit with a gastroenterologist the following day. *Id*. at 10. CT scan revealed uterine fibroid formation and "[p]artially collapsed right ovarian cyst with a small amount of free fluid." *Id*. at 11. She had "[s]table hemangioma in the right lobe of the liver." *Id*. An x-ray of her abdomen revealed "[n]o active disease in the chest[,] [t]he colon is at least mildly stool-filled[, and] [n]o bowel obstruction or perforation." *Id*.

On October 26, 2011, Ms. Dixon-Jones saw Dr. Mardiney at AAIC who noted that "she has been experiencing a ringing in the left ear intermittently and continues to experience intermittent sharp pain in the left ear." Ex. 26 at 26. The record further noted that she was also experiencing vertigo-like symptoms. *Id*. Her evaluation "revealed some inflammation of the pancreas and a cyst on the ovary" and her "pancreatic enzymes were elevated and her white cell count was 16,000." *Id*. Her physical examination was unremarkable. *Id*. The doctor's impressions were acute pancreatitis, which was improving, unspecified acute labyrinthitis,[8] and allergic diathesis[9], which was noted to be related to her flu vaccine. *Id*.

On November 1, 2011, Ms. Dixon-Jones saw a gastroenterologist with complaints of pain in the right upper quadrant and epigastric region. Ex. 12 at 26. The pain was "burning in nature and [went] into the left upper quadrant area and the back" beginning on October 23, 2011. *Id*. The record noted that Ms. Dixon-Jones had a "history of similar pain for the past several years." *Id*. The record also noted that she "attributes the present pain to taking a flu vaccine at work." *Id*. The doctor noted that her pain "is of uncertain nature" and that "[t]here is no clinical or biochemical evidence of pancreatitis [at that time], at least by [the doctor's] review[ ] of the lab work and/or imaging." *Id*. at 27.

[8] Inflammation of the internal ear which may be accompanied by hearing loss or vertigo. Dorland's at 995.

[9] Diathesis is a "condition of the body which makes the tissues react in special ways to certain extrinsic stimuli and thus tends to make the person more than usually susceptible to certain diseases." Dorland's at 512.

Ms. Dixon-Jones saw her allergist, Dr. Mardiney, again on November 2, 2011. *Id*. at 24. She was still experiencing intermittent vertigo symptoms, which worsened when riding in a car. *Id*. Her symptoms of left ear pain, which were noted to radiate into her left jaw, and her symptoms of intermittent popping of her left and right ears still persisted. *Id*. Ms. Dixon-Jones also complained of her right eye twitching for the past two weeks, which made her ability to focus difficult. *Id*. She noted that her short-term memory was affected. *Id*. Her abdominal pain, primarily in the right upper quadrant, persisted. *Id*. Dr. Mardiney no longer wanted Ms. Dixon-Jones to take Singulair as he noted its possible contribution to her vertigo symptoms. *Id*. He also noted his thought that Ms. Dixon-Jones' vertigo symptoms may be due to crystal imbalance in her inner ear. *Id*.

On November 4, 2011, Ms. Dixon-Jones saw an ear, nose, and throat ("ENT") doctor, Dr. Mark S. Schneyer, with complaints of dizziness and left ear pain. Ex. 20 at 4. Her vertigo intermittently occurred daily. *Id*. She also complained of her right eye twitching. *Id*. She described how her dizziness and imbalance affected her while sitting and riding in a car. *Id*. She also described the "piercing" pain in her left ear and how her hearing on the left side was worse as compared to her right side. *Id*. Such pain was worse when touched anywhere around her ear. *Id*. The record notes that she had "left ear pain since she had the allergic reaction to the flu shot" and that "[s]he started Prednisone for a severe allergic reaction to her flu vaccine[.]" *Id*. Her piercing pain "occurred intermittently every few days up to last Friday. Since then she has not had any piercing ear pain….She thinks the pain just dissipates on its own." *Id*. Petitioner also reported no headaches. *Id*. The doctor informed Ms. Dixon-Jones that her hearing was "completely normal" and he ordered electronystagmography[10] and videonystagmography testing. *Id* at 5.

Ms. Dixon-Jones had a GI follow up visit on November 8, 2011, and the record notes that her "endoscopic ultrasound examination showed a normal-appearing pancreas," the "pancreatic duct and the bile duct were not dilated." Ex. 12 at 37. Her HIDA scan revealed a normal common bile duct. *Id*. The doctor believed that she did not have evidence of chronic pancreatitis or acute pancreatitis, and "it appears that she may not have sphincter of Oddi dysfunction at this time." *Id*. The doctor further noted that "[b]efore proceeding to further invasive testing, [the doctor] believe[s] other etiologies of pain need to be looked into. Since [she] has thoracolumbar disease and a burning band-like pain which goes around her upper abdomen and back, her disc disease needs to be excluded." *Id*.

On November 15, 2011, Ms. Dixon-Jones visited Barenburg Eye Associates. Ex. 2 at 13. The purpose of her visit was due to dizziness, memory loss, and blurred vision. *Id*. The record notes that she received her flu vaccination on October 6, 2011, that she was in the process of undergoing tests and was temporarily disabled. *Id*.

Ms. Dixon-Jones had a laparoscopic hysterectomy on November 17, 2011. Ex. 8 at 107. On November 21, 2011, Ms. Dixon-Jones consulted with Dr. David J. Wang at St. Agnes Hospital for symptoms of palpitations and lightheadedness. *Id*. at 104. This consultation occurred after her laparoscopic hysterectomy, recurrent abdominal pain, and bleeding from her umbilicus. *Id*. Ms.

[10] Electornystagmogrophy is the "recording of changes in the corneoretinal potential due to eye movements, providing objective documentation of induced and spontaneous nystagmus." Dorland's at 602.

Dixon-Jones woke up with symptoms of lightheadedness, diaphoresis, and palpitations. *Id*. The record notes that Ms. Dixon-Jones had a diagnosis of primary pulmonary hypertension, recurrent supraventricular tachycardia, non-sustained ventricular tachycardia, and hypertension. *Id*. Dr. Wang reported that "[t]he exact etiology of the supraventricular tachycardia remains unclear […] but it is clear that is a reentrant tachycardia (reentrant atrial tachycardia versus atrioventricular nodal reentry tachycardia likely)." *Id*. at 105.

On November 19, 2011, Ms. Dixon-Jones was seen at Howard County General Hospital for bleeding at the surgery site. Ex. 10 at 28.

Ms. Dixon-Jones saw Dr. Schneyer again on November 20, 2011 for dizziness and imbalance. Ex. 20 at 2. This was a follow up visit after her electronystagmogram ("ENG"), which was normal. *Id*. The record notes that her symptoms have not improved, and Dr. Schneyer explained to her that he is unsure as to the cause of her symptoms and is unable to explain why her symptoms occurred after her flu vaccination. *Id*. The doctor noted that her inner ear appears to be functioning as normal, with a normal ENG and audiogram. *Id*. He informed Ms. Dixon-Jones that she should have her primary care physician set up an appointment with a neurologist. *Id*.

Ms. Dixon-Jones saw Dr. Mardiney on December 7, 2011. Ex. 26 at 22. At such time, she was "having some radiculopathy and [planned] to take her most recent MRI to her pain management specialist and will likely be referred to a neurosurgeon." *Id*. Her allergies were controlled, with the exception of experiencing some rhinorrhea and voice degradation, and she was prescribed Claritin for her rhinorrhea. *Id*.

On December 9, 2011, she saw Dr. Ogunsola for low back pain and abdominal pain. Ex. 16 at 23. She "complains of low back pain, radiating to right buttock, radiating to left buttock, radiating to right knee, and radiating to left knee. Associated symptoms include stiffness." *Id*. She described her pain as burning, aching, and constant. *Id*. She was also experiencing abdominal pain, including nausea and constipation, localized to her right and left upper quadrant. *Id*. She described her pain as sharp, constant, and unchanged, and the pain was worse when she walked. *Id*. The doctor notes that she "presents today for a follow-up assessment of chronic pain" and that she reports "pain in the bilateral low back and bilateral radiculopathy. This began >1 year ago" and she "describes the pain as worsening, constant, and burning.…The pain is made worse by standing and sitting." *Id*. at 24. Her pain is improved with medicine and nerve block injections. *Id*.

On December 19, 2011, Ms. Dixon-Jones saw a neurologist, Dr. Michael S. Sellman, for evaluation of her memory loss and vertigo. Ex. 18 at 15. The record described her prior medical history and symptoms, including her allergic reaction to the flu shot, dizziness, issues with her vision, hypertension, bleeding difficulties, and baseline fibromyalgia pain in her arms. *Id*. The record also noted that she did not completely heal from her hysterectomy. *Id*. Ms. Dixon-Jones did not exhibit any symptoms of memory loss and vertigo during evaluation. *Id*. at 16. Dr. Sellman noted that "she did not think she had memory problems, dizziness, or blurred vision today[,]" and described her as being "awake, alert, and oriented." *Id*. Ms. Dixon-Jones was able to read and speak fluently, with no signs of dysarthria. *Id*. She was also able to recall three out of three words in a three-minute time period. *Id*. Dr. Sellman noted that "it [was] speculative what event occurred

[in the] fall to cause Mrs. Dixon-Jones to intermittently have problems with memory loss as well as vision and balance." *Id*. Dr. Sellman noted that she had normal cranial nerve function, but she had difficulties with tandem walking. *Id*. The doctor ordered an MRI, a visual and auditory evoked response test, vestibular physical therapy, and cognitive rehabilitation. *Id*.

Ms. Dixon-Jones complained of lower back pain on January 9, 2012, which radiated to her right and left buttock and her right and left knee. Ex. 16 at 29. She described her pain as "burning, aching, and constant." *Id*. Her abdominal pain, including symptoms of nausea and constipation, was localized to her right and left upper quadrant, and described as "sharp, constant, and unchanged." *Id*. She was status post LESI (lumbar epidural steroid injection), which improved her low blood pressure, "but she continues to have generalized muscle weakness and fatigue and dizziness since her flu shot on 10/06/2011." *Id*. The record notes her appointment with a neurologist. *Id*. Her assessment notes that her pain is improving (by way of nerve block injections). *Id*. at 30. Her multi-disciplinary pain assessment notes that her pain screening and pain score are both 4 out of 10. *Id*. at 31. It also notes that her pain, described as burning and sharp, is located in her mid-back, which radiates around her abdomen, as well as bilaterally in her feet and legs. *Id*. Physical examination revealed "Facial puffiness" and her abdomen was "non[-]tender to palpation". *Id*. She had normal heel-toe gait pattern bilaterally. *Id*. Her face puffiness likely was due to steroids. *Id*. at 32. The record also notes her spondylosis, lumbago, cervical radiculopathy, and facet syndrome-lumbar were unchanged. *Id*.

Ms. Dixon-Jones saw Dr. Sellman again on January 19, 2012 for a re-evaluation of her memory loss and vertigo. *Id*. at 9. The notes indicate that she was dizzy while in the waiting room. *Id*. She informed the doctor about her appointment at Johns Hopkins rather than St. Agnes Hospital, due to a medical malpractice lawsuit against the gynecologist who performed her hysterectomy at St. Agnes Hospital. *Id*. She also informed the doctor of her history of posttraumatic stress disorder (PTSD)[11], which she stated developed in the year 2005 after an epidural injection – she blamed her memory loss for not reporting her posttraumatic stress disorder at her initial evaluation. *Id*. The doctor described Ms. Dixon-Jones as "awake, alert, [and] responsive[.]" *Id*. The doctor had her stand up and walk, which she was able to do; however, she was unable to perform tandem walking. *Id*. She was able to recall two out of three words in a one-minute time period, and one out of three words in a three minute time period. *Id*.

On January 21, 2012, Ms. Dixon-Jones saw her allergist, Dr. Mardiney, who noted that her allergy[12] and asthma were stable; however, she continues to experience issues with strength, balance, fibromyalgia, memory loss, dizziness, and blurred vision. Ex. 26 at 21. The doctor noted that "[h]er easy fatigability is suggestive of possible adrenal dysfunction[,]" and that he wants Ms. Dixon-Jones to be reviewed by an endocrinologist. *Id*.

January 23, 2012 was Ms. Dixon-Jones' first visit to Johns Hopkins Hospital Department of Physical Medicine and Rehabilitation ("Johns Hopkins Rehabilitation"). Ex. 27 at 70. She

[11] *But see* the impression of Dr. Jody Whitehouse on January 22, 2015: "I did not detect any significant psychopathology including Post-Traumatic Stress Disorder." Ex. 32 at 4.

[12] Ms. Dixon-Jones had an allergic reaction Thursday, January 19, 2012 while at a hair salon. Ex. 26 at 21.

complained of memory impairment, anomia, limitations on walking, dizziness while driving, and weakness. *Id*. at 71, 74.

On February 2, 2012, she went to Northwest Hospital Center for a right lower extremity venous Doppler, and the clinical indication notes pain and swelling. Ex. 11 at 48. There was "no evidence of right lower extremity DVT." *Id*.

On February 6, 2012, she saw Dr. Ogunsola for a follow up visit. Ex. 16 at 34. HPI notes her complaints of low back pain that radiates to her right and left buttocks as well as her right and left knees. *Id*. It also notes her history of abdominal pain. *Id*. Ms. Dixon-Jones was status post LESI, which helped her low blood pressure; however, she "continues to have generalized muscle weakness and fatigue and dizziness since her flu shot on 10/06/2011." *Id*. Pain assessment notes that she is following up for her chronic pain, and that she has had "[w]orsening weakness and fatigue since October" and "[b]urning sensation in the mid back and abdomen." *Id*. at 35. Multi-disciplinary pain assessment notes that she is currently in pain, the location being bilateral feet, and mid back which radiates around the abdomen. *Id*. at 36. Duration of pain is greater than six months and the pain is characterized as burning and sharp. *Id*. Physical examination revealed facial puffiness and her abdomen was "non[-]tender to palpation." *Id*. Her gait was slow and calculated. *Id*. She had palpation-spinal tenderness, described as mild, in her mid-lower back. *Id*. at 36. Range of motion for forward flexion was 20 degrees and 10 degrees for hyperextension. *Id*. Her ability to toe walk, heel walk, and raise her legs straight out from a sitting position was normal. *Id*.

Ms. Dixon-Jones saw her neurologist, Dr. Sellman, on February 17, 2012 with multiple complaints, including short-term and long-term memory loss as well as "staring for no apparent reason." Ex. 18 at 7. At this time, she attended memory loss therapy at Johns Hopkins and was also seeing a psychologist at Johns Hopkins. *Id*. It was noted that she had a neuropsychological test, but there was no documentation of the results – Dr. Sellman requested that she bring the results at her next visit so that he could review the results. *Id*. Her examination revealed Ms. Dixon-Jones to be awake and alert; however, she had difficulties with calculations. *Id*. The doctor noted that she was able to recall the year, place, and person, as well as three out of three words in both a one-minute and three-minute time period. *Id*. The doctor also noted a normal cranial nerve function, and that Ms. Dixon-Jones was able to walk slowly. *Id*. Ms. Dixon-Jones informed the doctor that "she was having diffuse pain throughout her entire body from fibromyalgia." *Id*. An EEG was reported as normal, and no seizures were recorded. *Id*. at 18.

Ms. Dixon-Jones saw Dr. Sellman on March 14, 2012. *Id*. at 5. She revealed that she was in "a great deal of pain[,]" and that "her pain management doctor is not able to help her." *Id*. At this time, the memory treatments at John Hopkins are noted to be terminated as her therapist informed her that treatment would not be effective due to the amount of pain she was experiencing. *Id*. Dr. Sellman noted that he still did not have records of Ms. Dixon-Jones' neuropsychological testing, although she informed him that someone in the office confirmed that he received such records. *Id*. She informed him that she would bring him physical copies of the records. *Id*. Upon examination, the doctor noted that Ms. Dixon-Jones "appeared situationally depressed[,] appeared uncomfortable[,] and complained bitterly of pain due to her fibromyalgia." *Id*. The record notes that Dr. Sellman referred Ms. Dixon-Jones to Johns Hopkins Bayview Hospital's Memory and

Alzheimer's Treatment Center as it was his opinion that such treatment center would be the best place to treat her symptoms. *Id*.

On April 18, 2012, Ms. Dixon-Jones went to Johns Hopkins Rehabilitation. She informed her therapist, Dr. Kortte, that she had been experiencing cognitive and emotional difficulties, and attributed such difficulties to her adverse reaction to the flu shot. Ex. 27 at 32. The goal of her therapy sessions was to "improv[e] her pain and fatigue management and maximize[e] her cognitive functioning, facilitating her emotional adjustment." *Id*. During her therapy session, Ms. Dixon-Jones mentioned her issues with sleeping and pain, and "verbalize[d] the synergistic relationship between her sleep and pain difficulties and how these also affect and are influenced by her frustration levels." *Id*. The notes inidicate she experienced adverse reactions to Ambien and had discontinued it, but was currently taking Lunesta that did not provide much relief. *Id*. She was also taking Zonegran to control her pain, but she mentioned that "[s]he does not find that anything attenuates her pain." *Id*. She described her pain as a constant burning sensation that migrates to different areas of her body as well as a cold sensation in her left hand. *Id*. Her diagnosis was "late effect of adverse effect of drug, medicinal, or biological substance." *Id*. at 33.

On April 26, 2012, Ms. Dixon-Jones saw Dr. Sellman who indicated that she was scheduled to undergo neuropsychological testing by Dr. Newman. Ex. 18 at 3. She informed the doctor of her wishes to see a pain management specialist as she "feels that she has reflex sympathetic dystrophy."[13] *Id*. She mentioned having minor issues with her arms, which were being controlled with Lyrica as prescribed by her pain management specialist, Dr. Ogunsola, whom she expressed she no longer wanted to visit. *Id*. Dr. Sellman informed Ms. Dixon-Jones that he has "no experience in her specific allegations that she is having problems as a complication of the flu shot[,]" and he requested that she "continue endeavoring to find a physician with experience in [that] disorder." *Id*. at 3-4. In regard to symptoms of memory loss, Ms. Dixon-Jones agreed to visit the doctor again after neuropsychological testing. *Id*. at 4.

On April 30, 2012, Petitioner visited the Johns Hopkins Rehabilitation. She saw Dr. Michelle Kramer (Psy.D.) During this visit, Dr. Kramer noted concerns "regarding [Ms. Dixon-Jones'] continued belief that she will find a neurologist who will diagnos[e] her properly, find a treatment and significantly decrease her pain[.]" Ex. 27 at 29. Ms. Dixon-Jones mentioned her prior experiences with chronic pain in the past and her ability to manage such pain, but the current pain she was experiencing "is 'different' and she described the intensity as unbearable, intolerable and the cost of misery too high." *Id* at 30. She further mentioned that "[s]he has become more independent from her husband over the last few months and she attributes [that] to improved physical functioning after surgical recovery and improved cognition after discontinuing opioid use." *Id*. Her diagnosis was "late effect of adverse effect of drug, medicinal, or biological substance." *Id*.

On May 7, 2012, she reported that her muscle pain, weakness, fatigue, and dizziness were unchanged and also reported "tingling and piercing sensation in random areas." Ex. 16 at 49. She was still having problems with her memory loss. *Id*. The assessment notes that her physical therapy had been unhelpful. *Id*. at 50.

[13] CRPS was formally known as reflex sympathetic dystrophy. *See* Ex. C at 1.

On June 14, 2012, Ms. Dixon-Jones saw a neurologist, Dr. Walter E. Kozachuk, with several complaints, including headaches, cognitive dysfunction with decreased recent memory, dysphasia with word finding difficulty and word substitution, disequilibrium and intermittent vertigo, generalized myalgias in the upper extremities, pain and paresthesias of the upper extremities, fatigue along with decreased physical endurance and insomnia, and loss of function with inability to perform her prior job in nursing. Ex. 24 at 1.

Dr. Kozachuk noted Ms. Dixon-Jones' post-vaccination medical history and symptoms in great detail. The record noted that she had bilateral arm tremor while sleeping and did not experience such tremor while awake. Ex. 24 at 2. She informed the neurologist that she was terminated from her place of employment due to her inability to perform some of her tasks. *Id*. She also informed the neurologist of her rehabilitation and vestibular training, which she stated was not effective. *Id*. She also complained of chronic generalized headaches since her flu vaccination. *Id*. Her examination revealed mild acute distress along with pain and anxiety. *Id*. at 3. Her speech, which was fluent, and her free gait, which was normal, were both noted as slow. *Id*. Her "tandem and single leg standing were mildly impaired[, her] Romberg sign and cerebellar exam was normal[, her] [c]ranial nerves were normal with no nystagmus or VI nerve palsy." *Id*. She had normal cervical range of motion with no pain on palpation, and there was no pain on palpation of her thoracic or lumbar spine. *Id*. Her "[s]ensory exam in the hands to touch [was] normal" and "Tinel's sign was normal in the elbow and wrists." *Id*. She had no pain palpation in her trapezius muscles, and the range of motion in her shoulders was normal. *Id*. "Motor exam of the arms was normal." *Id*. Dr. Kozachuk's impression mostly mirrored Ms. Dixon-Jones' list of complaints, with the addition of "[p]ost vaccination symptoms of acute anaphylaxis with chronic symptoms of headache[,] [a]bnormal neurological exam with increased reflexes in the legs with spread and body myoclonic jerks[,] patient's physical symptoms of chronic pain and cognitive dysfunction show direct causation to the accident of 10-6-11[, and] [t]he patient is totally and temporarily disabled." *Id.* at 3-4. (Emphasis omitted).

Ms. Dixon-Jones had a follow up visit with Dr. Kozachuk on July 25, 2012. Ex. 24 at 5. The doctor reviewed records from Johns Hopkins University and found that "there was no diagnosis for the etiology of her dysequilibrium." *Id*. Examination of Ms. Dixon-Jones revealed "no change in the physical exam and no new focal symptoms." *Id*. Dr. Kozachuk scheduled an electromyography ("EMG") of her upper extremities to rule out gammopathy or sensory neuropathy. *Id*. at 8.

Ms. Dixon-Jones had an EMG on August 22, 2012. Ex. 7 at 2. The results were normal, and it was reported that "[e]lectrodiagnostically there was no evidence for a large fiber neuropathy, a left [upper extremity] entrapment neuropathy[,] or for a left cervical radiculopathy at [that] time." *Id.* at 3. Such results were acknowledged by Dr. Kozachuk during Ms. Dixon-Jones' follow up visit with him on September 13, 2012. Ex. 24 at 9. At that visit, Ms. Dixon-Jones reported "recurrence of left facial rash and pruritis." *Id*. She stated that she experienced an increase of pain in her extremities and trunk. *Id*. She also stated that she had burning dysesthesias of her arms, with sensation being greater in her left arm as compared to her right arm. *Id*. She reported an increase in severity of her disequilibrium. *Id*. The record mentioned a new onset of sleep difficulty, specifically moderate insomnia and her not feeling refreshed after she sleeps. *Id*. at 10.

The doctor noted that she is undergoing pain management treatment for her fibromyalgia. *Id*. Examination of Ms. Dixon-Jones revealed "no change in the physical exam and no new focal symptoms." *Id*.

On September 17, 2012, Ms. Dixon-Jones was seen at Howard County General Hospital for a lumbar puncture and to rule out Alzheimer's disease. Ex. 10 at 21.

On September 28, 2012, Ms. Dixon-Jones had a quantitative electroencephalography ("Q-EEG") or brain mapping. Ex. 26 at 50. The unusual features of this testing revealed that Petitioner showed "very significant slowing in the posterior area of the cortex, parietal to occipital lobes … slowing in the left and right temporal lobes … slowing in the frontal cortex … in what appears to be a coup-contracoup injury"[14] as well as "damage in cortical function … affecting ability to think in abstract concepts or connections." *Id.*

Ms. Dixon-Jones went to Nasseri Clinic of Arthritic & Rheumatic Diseases ("Arthritic & Rheumatic Clinic") on February 14, 2013 in order to rule out polymyalgia rheumatica ("PMR"). Ex. 3 at 6. The record noted that she was a patient of such clinic who had not been seen in several years. *Id*. The record provided a brief overview of Ms. Dixon-Jones' medical history, including her diagnosis of fibromyalgia syndrome in 2006 and her reported diagnosis of posterior reversible encephalopathy syndrome ("PRES") following her flu vaccination. *Id*. Her current complaints were "intermittent burning pain in her bilateral shoulders, thighs, or knees, also increased fatigue." *Id*. Ms. Dixon-Jones mentioned that she has a history of a rash located on her right cheek, which was not present during the time of her visit, but she was able to provide pictures. *Id*. It appears the rash would resolve on its own within one to two weeks. *Id*. She further mentioned her history of having headaches, describing it as diffuse, and associating her headaches with her symptoms of dizziness. *Id*. She denied that numbness and tingling were associated with her headaches. *Id*.

The record noted that Ms. Dixon-Jones was not currently on medication for her fibromyalgia, but she would take Dilaudid, prescribed by pain management, for breakthrough pain. *Id*. She was assessed with having pain in her joints located at multiple sites. *Id*. at 7. The doctor found "little subjective or objective evidence of inflammatory arthritis or specifically PMR[,]" and believed that "it [was] likely her symptoms which also include numerous trigger points on upper and lower extremities are a flare of her previously diagnosed fibromyalgia." Nonetheless, the doctor planned to conduct extensive laboratory testing in order to rule out the possibility that her diffuse arthralgias and myalgias were caused by inflammation or infections. *Id*. The doctor also planned to look for any secondary causes for her fatigue. *Id*.

On February 18, 2013, Ms. Dixon-Jones had a MRI of the thoracic spine, which revealed "degenerative disk and small central disk herniation T8-T9." Ex. 13 at 19. In comparison to her October 4, 2009 examination, "there are mild degenerative changes of the cervical and thoracic disks. There is narrowing at the T8-T9 level, with a central disk protrusion. This appears to be slightly more prominent than the previous study." *Id*.

[14] A coup is defined as "a blow or attack." Dorland's at 426. A contrecoup is an "injury resulting from a blow on another site, especially of the brain…." *Id.* at 410.

Ms. Dixon-Jones saw an optometrist, Dr. Joshua Gordon, on February 19, 2013. Ex. 2 at 11. A diagnosis of PRES was noted in her health history as well as a diagnosis of fibromyalgia. *Id*.

On November 19, 2013, Ms. Dixon-Jones visited Dr. Patrick Okolo and was diagnosed with gastrointestinal dysmotility. Ex. 27 at 2. The comments section of this record notes "brain swelling after flu vaccine." *Id.* at 13.

On March 3, 2013, Petitioner went to the ED complaining of syncopal episode associated with seizures. Ex. 10 at 9. The summary of her care at the ED stated, "Return for recurrent episodes of passing out. You are dehydrated." *Id.* at 15.

On March 20, 2013, Ms. Dixon-Jones followed up with Dr. Nasseri at the Arthritic & Rheumatic Clinic, and she had complaints of "shoulder pain and burning sensation in her bilateral thighs." Ex. 3 at 1. She also stated that she has headaches in the occipital area on a daily basis. *Id*. The doctor noted that she has "a history of fibromyalgia syndrome, and when seen [on February 14, 2013], extensive laboratory testing was done to rule out the possibility of an inflammatory arthritis." *Id*. The doctor, after a review of her laboratory testing results, noted that her results were normal "with the exception of a very mildly elevated high-sensitivity CRP of 8." *Id*. The doctor's assessment was joint pain located in multiple sites. The doctor "[did] not believe that she has a PMR or temporal arteritis" as it was unknown in patients under the age of fifty and Ms. Dixon-Jones, at that time, was forty-five years old. *Id*. at 4. In regard to the laboratory testing, there was "no evidence of an inflammatory arthritis" and the doctor believed that her symptoms "are an exacerbation of her previously diagnosed fibromyalgia […] [The doctor] believe[s] that her fibromyalgia is very severe." *Id*. The doctor notes that Ms. Dixon-Jones "has previously failed Lyrica and Cymbalta and has been advised by her neurologist and pain management specialist not to take Savella." *Id*.

Ms. Dixon-Jones had a whole-body scan, ordered by Dr. Nasseri, on March 28, 2013 to evaluate for reflex sympathetic dystrophy (CRPS). Ex. 11 at 41. Her bone scan findings provide the following: "Flow images of pelvis and thigh appear normal. Immediate blood pool images of lumbar spine, pelvis, thigh, knees and feet are obtained which are also unremarkable….Mild degenerative change bilateral shoulders and first MTP joint right foot. Uptake in rest of the skeleton is unremarkable." *Id*. In conclusion, she had "[n]o bone metastases" and "[n]o scintigraphic evidence of reflex sympathetic dystrophy." *Id*.

On April 12, 2013, Ms. Dixon-Jones had a gastroenterology consultation due to having a two- to three-day history of upper abdominal pain, nausea, and periodic vomiting. Ex. 10 at 192. She "describes the pain to be cramping in nature and accompanied with nausea and feverish feeling." *Id*. She also had constipation. *Id*. Review of symptoms indicated that she has had headaches, a dizziness spell with seizure, and chronic pelvic pain. *Id*. at 193. Radiology revealed no evidence of pancreatitis, hepatic hemangiomas were noted; her abdominal ultrasound was normal. In his discharge report, Dr. Charles Moore noted: "Likely this patient has underlying scar tissue as a potential course of the pain along with the possibility of there being some contributory chronic back pain." Ex. 11 at 170.

On May 3, 2013, Ms. Dixon-Jones complained of low back pain that radiates to her right buttock and left buttock, as well as her left and right knees. Ex. 16 at 91. She also reports abdominal pain, and generalized burning sensation in her shoulder, hip, knee, and feet. *Id*. "She reports today that she has a Sphincter of Oddi dysfunction." *Id.*; *see* Ex. 12 at 37 (visit on November 8, 2011, which states "patient also underwent a HIDA scan whereby the study was done to look for sphincter of Oddi dysfunction. The study revealed normal common bile duct").

Ms. Dixon-Jones saw Dr. Eric H. Williams on June 17, 2013, "with a complaint of bilateral upper extremity pain and weakness that has been present for several years." Ex. 127 at 32. She reported pain in her neck and shoulders, numbness and tingling in her hands, and burning, searing, and prickling pain in the backs of her hands. *Id*. She also reported fatigue and weakness. *Id*. She informed Dr. Williams of her EMG results, which revealed she had thoracic outlet syndrome. *Id*. "She presents today to try to identify any potential causes of her persistent upper extremity arm weakness and pain." *Id*. Right and left palpation revealed "tender scalene anticus" and right and left Tinel exam revealed "tinel over scalene anticus and roos maneuver positive" as well as "tinel over radial tunnel and tenderness over radial tunnel." *Id*. Right and left vascular revealed "normal color and temperature and no varicosities and radial pulse 3/4." *Id*. at 33. Dr. Williams assessed her with pain in limb and the doctor ordered an MRI of the brachial plexus and referred her to neurology. *Id*.

On July 3, 2013, Ms. Dixon-Jones had a gastroenterology follow up visit, which occurred post-endoscopy and colonoscopy. Ex. 12 at 52. The medical record notes that she "was seen in our office on June 5, 2013 for these symptoms and it was [the doctor's] assessment that [she] was having accentuation of her reflux from unknown factors and also accentuation of her IBS because of the opiates that she has been taking for her pain." *Id*. The doctor stated that his impression was that her "chronic pain may be related to IBS with constipation accentuated by opiate dependence, but gastroparesis may be playing a role as well and that there was no evidence of chronic pancreatitis at the present time." *Id*. at 53.

Ms. Dixon-Jones had surgery on July 10, 2013. Ex. 5 at 64. The procedure performed is noted as "[d]iagnostic laparoscopy, lysis of adhesions, bilateral salpingo-oophorectomy, fulguration of stage I endometriosis." *Id*. Her postoperative diagnosis was "[s]tage I endometriosis, intra-abdominal adhesions." *Id*.

Ms. Dixon-Jones saw Dr. Christopher L. Fortham on January 7, 2014 due to bilateral shoulder pain and stiffness that began in the summer of 2013. Ex. 17 at 13. Physical examination revealed that, generally, her skin and subcutaneous tissues of both arms were normal. *Id*. "Peripheral pulses are palpable, bounding, and symmetric at the wrists. Both shoulders appear normal." *Id*. at 13. She was unable to touch her thoracic spine, and she had "reasonable cuff strength with resisted abduction and resisted external rotation – no lag signs." *Id*. Her radial artery was palpable. *Id*. "She has sensibility in the axillary distribution as well as in her fingers." *Id*.

The doctor also examined Ms. Dixon-Jones' hands, which revealed "no discernible misalignment, asymmetry, crepitation, tenderness, masses, effusions or prominence." *Id*. Her range of motion "is satisfactory without pain, crepitation or contracture." *Id*. All of her joints

were stable, and her muscle strength and tone were satisfactory. *Id*. "In summary, [she] has severe bilateral shoulder adhesive capsulitis." *Id*. at 14.

On February 14, 2014, Ms. Dixon-Jones had surgery (right shoulder scope capsular release) due to right shoulder pain. Ex. 15 at 89. Her postoperative diagnosis was adhesive capsulitis. *Id*.

On July 21, 2014, Ms. Dixon-Jones had a follow up gastroenterology visit. Ex. 14 at 7. The medical record notes that she had symptoms of chronic nausea with known vestibular dysfunction, GERD and intermittent left upper quadrant abdominal pain. *Id*. The record also notes that "she is recovering from right shoulder surgery" on June 20, 2014 ("R shoulder arthroscopic debridement, lysis of adhesions and decompression with regular physical therapy"). *Id*. She denied having epigastric pain at this time. *Id*. Doctor's assessment and plan notes that her "nausea is likely multifactorial with vestibular dysfunction and chronic opiate use being the most likely etiologies." *Id*. at 12. "Chronic narcotic use can certainly cause delays in the GI tract…which can exacerbate symptoms of nausea and bloating." *Id*. "A trial of neuromodulators may decrease her narcotic requirement as her pain is partially neuropathic in nature (known disc disease, fibromyalgia, etc)." *Id*. The doctor believes that her nausea is caused by "a combination of vestibular dysfunction and narcotic use." *Id*. at 13.

Ms. Dixon-Jones saw Dr. Williams on August 21, 2014 to follow up with her complaints of skin sensation disturbance, hand joint pain, and pain in limb. Ex. 127 at 15. Her physical examination results are similar to her exam on June 17, 2013 (*id*. at 32), with the addition of having a frozen shoulder that would not lift beyond 45 degrees. *Id*. at 18. Dr. Williams assessed her with pain in limb and radial neuropathy. *Id*. at 19.

On October 13, 2014, Ms. Dixon-Jones saw Dr. Aradillas due to experiencing "terrible pain." Ex. 23 at 6. Physical examination revealed "right shoulder is in spasm, left shoulder is dropped, obvious livedo reticularis worse at the legs than the arms...." *Id*. at 6. She was positive for the following:

> Roos' and Wright's brachial plexus abduction maneuvers[;] Tinel's signs at the supraclavicular fossa, the C2 point and the distal clavicle as well as in the neurovascular bundle and the Arcade of Froshe on the left arm and right arm[;] joint pain, and deep sensitization and [] allodynia, mechano more than thermos and the dynamic is worse.

Id. at 7. She was positive for the following pain processing: "spread and loss of surround inhibition[;] hyperpathia and [] hyperalgesia. Upon sensory exam there was a decreased sensory on a lateral cord distribution bilaterally and a clear glove distribution of loss of pain and temperature up to the level of the mid forearm bilaterally." *Id*. Her right arm was swollen throughout and evident at the hand and forearm, and she had purplish discoloration in both of her hands. *Id*. There was "[n]o local temperature difference between left and right" and there was "local diaphoresis at both hands right worse than left." *Id*. Dr. Aradillas states that she had "clear decrease in sensation small fiber modalities in a glove and stocking distribution," which is not a consequence of her long term depression, but rather from a neuropathic process. *Id*. at 8. She had abnormal triple response of Lois. *Id*. Dr. Aradillas assessed Ms. Dixon-Jones with CRPS, SFN,

and noninfectious acute disseminated encephalomyelitis ("ADEM"). *Id*. His plan was for her to have a skin biopsy and blood work for possible SFN. *Id*. Dr. Aradillas stated that she was a good candidate for ketamine infusions. *Id*.

On February 11, 2015, Ms. Dixon-Jones had a consultation at Mercy Health Services with Dr. David Maine. Ex. 33 at 3. She complained of mid and low back pain, which started in her mid back and radiated to her low back. *Id*. Occasionally, the pain radiated down her right leg, but she reported that it did so infrequently. *Id*. The record notes that she "has been diagnosed with posterior reversible encephalopathy syndrome, as well as a brain injury to the occipital, right frontal and corpus callosum." *Id*. The record also notes her "history of brain paresthesia, cyclic vomiting syndrome, and a diagnosis of complex regional pain syndrome." *Id*. She goes to Pennsylvania for ketamine infusions. *Id*. "She has also been diagnosed with vertigo, severe fibromyalgia, chronic fatigue syndrome, as well as a brachial plexus entrapment syndrome in the setting of a previous motor vehicle accident." *Id*. She rates her pain a six out of ten. *Id*.

Review of symptoms states that she reports weight gain, shortness of breath, irregular heartbeat, leg swelling, numbness and tingling, headaches, coordination loss, weakness, heartburn, constipation, depression, sleep disturbances, irritability, and mood swings. *Id*. at 5. Physical examination revealed that she "has no tenderness to palpation along the spinous processes[;]" however, she "has an area in the right paraspinal musculature, toward the thoracolumbar junction where she has focal tenderness. She appears to have acute trigger points in this region." *Id*. Continuing the physical examination, the doctor notes that she "has no tenderness on palpation toward the lumbosacral junction or the paraspinal musculature….Strength testing is 5/5 in the EHL, gastrocnemius, tibialis, and quads." *Id*. "Her extremities are warm to touch. There is no edema….no pain with internal rotation of either hip. There is no tenderness over the SI joint." *Id*. There was no allodynia, "at least in her lower extremities." *Id*. The doctor's impression was "chronic pain syndrome." *Id*.

On May 25, 2016, Petitioner again visited Dr. Aradillas. The physical exam portion of the visit is identical to the physical exam section detailed in the October 13, 2014 visit (Ex. 23 at 6-8). Dr. Aradillas assessed Petitioner with CRPS, SFN, and neuropathic spondylopathy of lumbar spine. Ex. 125 at 39. Dr. Aradillas again confirmed the need for a skin biopsy (presumably to diagnose SFN). *See id.*[15]

On March 1, 2016, Ms. Dixon-Jones had a follow up visit at National Spine & Pain Centers ("Spine & Pain") for her herniated disc. Ex. 120 at 35. She had been receiving epidural steroid injections and reported "significant improvement in the left side" and complained of "pain primarily on the right" that "radiate[d] from the lower back into the right lateral foot." *Id*. at 36. MRI revealed disc protrusion on her right side at the L4-5 level. *Id*.

On December 7, 2016, Ms. Dixon-Jones had a follow up visit at Spine & Pain for her herniated disc. Ex. 120 at 4. The record notes that her lower back and right leg pain were symptoms secondary to a L5-S1 disc herniation. *Id*. The record also notes her history of CRPS in her left arm. *Id*. at 5.

[15] Dr. Aradillas did not perform the skin biopsy. *See* Tr. at 159.

Ms. Dixon-Jones had a follow up visit at Spine & Pain on April 27, 2017. Ex. 120 at 48. The doctor's impression notes that "[a]t L5-S1 there was mild bilateral foraminal compromise secondary to disc bulge and facet hypertrophy. This could account for the radicular symptoms in the leg." *Id*. at 49. Regarding her CRPS, the record notes that she was "receiving ketamine injections to the neck region for the CRPS in the left arm." *Id*. at 50.

On November 15, 2017, Ms. Dixon-Jones had a follow up visit at Spine & Pain for her spondylosis in her lumbar region. Ex. 120 at 1. At this visit, she reported that her pain was better with medication and treatment, and she described her pain as intermittent throughout the day. *Id*. Her pain was burning, chronic, sharp, and radiating. *Id*. Associated symptoms were weakness and stiffness. *Id*. The medical record discusses her history of lower back and right lower extremity pain due to her L5-S1 disc herniation, and notes that she "has a history of CRPS in the left arm" that began after her flu vaccination. *Id*. at 1-2.

III. Fact Testimony

Ms. Dixon-Jones testified at hearing. She described her health and medical condition both before and after her October 6, 2011 flu vaccination. Before the vaccination, Petitioner testified that she and her husband used to host Thanksgiving dinner and Christmas brunch for approximately 30 people. Tr. at 14. After the vaccination, they no longer hosted either event. *Id.* at 16.

Ms. Dixon-Jones also discussed various activities that she used to enjoy that she has needed to modify since her flu vaccination. For example, she and her husband enjoy camping. They still go camping, but Ms. Dixon-Jones no longer rides her bike as much as she used to during these trips. Tr. at 21. She also no longer hikes. *Id.* at 22. In addition to camping, Ms. Dixon-Jones testified that she used to enjoy cross stitch, shopping, and gardening. *Id.* at 22-23. After her flu vaccination, she no longer does cross stitch, and she has limited her shopping and gardening. *Id.*

Ms. Dixon-Jones testified that she is not confident in her memory regarding the timing of her medical symptoms and medical events. Tr. at 23-24. She stated that she did agree with the timeline of symptoms recorded in her medical records. *Id.* at 24. Ms. Dixon-Jones testified briefly about the VAERS report that was filed in this case, and specifically about the fact that "first time flu shot" was handwritten on that record. Ms. Dixon-Jones testified that she did not fill that form out and does not recall telling the nurse that it was her first flu vaccination. *Id.* at 25. She testified that she has received a total of two flu vaccinations. *Id.*

Petitioner discussed the treatment she has been receiving from Dr. Aradillas and testified that these treatments have helped her, although she is still not back to her state of health from before the flu vaccination. Tr. at 27-28.

IV. Expert Opinions

A. Dr. Enrique Aradillas-López

Petitioner filed one expert report from Dr. Aradillas, and he also testified at the hearing. *See* Expert Report, filed as Ex. 37 (ECF No. 26-1), hereinafter "Aradillas Rep.".

Dr. Aradillas received his medical degree from La Salle University of Medicine in Mexico City, Mexico. *See* Aradillas CV, filed as Ex. 38 (ECF No. 26-2) ("Aradillas CV"). He completed his internal medicine residency at Interfaith Medical Center in Brooklyn, New York, and a residency in neurology at the Drexel University College of Medicine in Philadelphia, Pennsylvania. *Id.* at 1. Following his residencies, Dr. Aradillas completed an interventional pain management fellowship at Penn State University in Hershey, Pennsylvania. *Id.* Dr. Aradillas is board certified in neurology, and holds a position as an assistant professor, and the Chief of the Division of Pain in the Department of Neurology at Drexel University. *Id.*

Currently, Dr. Aradillas works as the director of the Neuropathic Pain Center at the Vincera Institute in Philadelphia, Pennsylvania. Aradillas Rep. at 1. For the past six years, Dr. Aradillas has treated patients with chronic neuropathic pain, particularly CRPS and SFN. *Id.* In his practice, Dr. Aradillas has evaluated several thousand patients with CRPS. *Id.* In collaboration with Drexel University, Dr. Aradillas has several grants, two with the National Institutes of Health, and one pharmaceutical grant to study a new therapy for CRPS. He has published several articles in the areas of pain and CRPS. Aradillas CV at 3-4. I recognized Dr. Aradillas as an expert in neurology and CRPS.

In his report and at the hearing, Dr. Aradillas opined that Petitioner developed CRPS as a result of the flu vaccine she received on October 6, 2011. Aradillas Rep. at 2.

1. Budapest Criteria

According to Dr. Aradillas, CRPS is a chronic and incurable condition, which affects the central nervous system (or the entirety of the spinal cord). Tr. at 51-52. The Budapest Criteria are well accepted in the medical community as the diagnostic criteria for CRPS. *Id.* at 45. The Budapest Criteria were validated by an article written in 2009 entitled, "Validation of proposed diagnostic criteria (the ''Budapest Criteria") for Complex Regional Pain Syndrome."[16] The criteria include:

1) Continuing pain, which is disproportionate to any inciting event
2) Must report at least one symptom in three of the four following categories:
   - Sensory: reports of hyperesthesia and/or allodynia
   - Vasomotor: reports of temperature asymmetry and/or skin color changes and/or skin color asymmetry

[16] Harden RN, et al. Validation of proposed diagnostic criteria (the "Budapest Criteria") for Complex Regional Pain Syndrome. PAIN 2010; 150: 268-74 (filed as Ex. 39; hereinafter referred to as Ex. 39).

- Sudomotor/edema: reports of edema and/or sweating changes and/or sweating asymmetry
- Motor/trophic: reports of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)

(3) Must display at least one sign at time of evaluation in two or more of the following categories:

- Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch and/or deep somatic pressure and/or joint movement)
- Vasomotor: evidence of temperature asymmetry and/or skin color changes and/or asymmetry
- Sudomotor/edema: evidence of edema and/or sweating changes and/or sweating asymmetry
- Motor/trophic: evidence of decreased range of motion and/or motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin)

(4) There is no other diagnosis that better explains the signs and symptoms

The diagnosis for CRPS is made clinically, meaning that it "is made only based on symptoms and physical exam findings." Tr. at 45. Since CRPS is a clinical diagnosis, there is no test that can be performed to diagnose it. *Id.*

In addition to explaining the four categories listed in the Budapest Criteria, Dr. Aradillas described how he determines whether his patients have signs of the disease. Regarding the sensory category, Dr. Aradillas testified that he examines his patients by using "a tuning fork to test for cold allodynia, and the tuning forks are usually cold, so if [the patient] report[s] that it hurts, then that's enough…for the physical exam finding, or if the pinprick hurts more than [expected], then that's also enough for the physical exam finding part." Tr. at 48. Regarding the vasomotor category, he looks for skin color changes or skin color asymmetry. *Id.* at 48-49. Regarding temperature asymmetry, Dr. Aradillas "usually send[s] [patients] to get another specialized test.…[He doesn't] have a thermometer in the office." *Id.* at 49. Regarding the sudomotor and edema category, he compares the extremities and looks for swelling. *Id.* Dr. Aradillas performs "a neurological examination, motor exam, and determine[s] if there's weakness or not. And then for the skin and nails and hair changes, [he] just inspect[s] the patient [to] see if [he] find[s] any of this." *Id.* In his practice, Dr. Aradillas states that about 30% of his patients present with obvious clinical changes while the remainder of his patients have more subtle changes. *Id.* at 50.

Citing medical literature, Dr. Aradillas noted that a characteristic of CRPS is pain spread. Spread of pain occurs in part because "irreversible activation of the postsynaptic nerve happens not only on the level of injury, but there is a communication within these neurons in the spinal cord which eventually leads to the activation of the postsynaptic neuron at all levels of the spinal cord." Tr. at 73. Describing the pain that CRPS patients experience, Dr. Aradillas testified that individuals "will develop this natural wear and tear of the body, but because the whole pain system is now sensitized, this new or this chronic pain -- normal chronic pain condition in a patient with CRPS will be experienced [as] extra painful." *Id.* at 74. Further, "this extra input of pain…because there's still a message of pain that is going into the spinal cord, will continue to perpetuate these changes." *Id.*

2. CRPS Diagnosis

Dr. Aradillas saw Petitioner for the first time on October 13, 2014. S*ee* Ex. 23 at 6-9. He testified that Petitioner fulfilled the "symptom requirement" of the Budapest criteria during this initial visit because:

> [s]he complained to me of pain that was continuous, that started after she received the flu vaccine on October 6th of 2011. So she had that….She also complained to me at that time of pain to touch. She complained to me of hugs, specifically. She didn't like people hugging her, touching her, because that really hurt. She also admitted to have noted that her extremities at times were cold or hot. She also said to me that she has noticed, during the course of those three years, swelling that came and went, and she complained to me of severe upper extremity weakness, especially in the hands and some of it in the lower extremities, but most notably in the hands….She basically had a complaint on each one of the symptom categories, sensory, the vasomotor category, the sudomotor category, and the motor and trophic category.

Tr. at 114-15.

He further testified that Petitioner fulfilled the "signs requirement" of the Budapest criteria based on his findings during her physical examination. Tr. at 115. Regarding the sensory category, Dr. Aradillas found that Petitioner had positive Roos and Wright brachial plexus abduction maneuvers, positive Tinel sign, positive Arcade of Frohse, joint pain, deep sensitization, and allodynia.[17] *Id.* at 115-16. She also had hyperpathia and hyperalgesia. *Id.* at 118. Regarding the vasomotor category[18,19], Dr. Aradillas found that Petitioner had glove distribution (loss of sensation to pain and temperature), loss of sensation to pain in the hand, and temperature on the right and left sides.[20] *Id.*

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[17] Dr. Aradillas describes Roos and Wright as "a maneuver that stretches the brachial plexus. If you have a brachial plexus injury, then you will have a positive Roos and Wright abduction maneuver." Tr. at 115-16. He states that a Tinel sign "refers to a sensitized peripheral nerve that you can press on that is proximal -- in close proximity to the surface, so you can press on it. The most common Tinel sign or the most well known happens when you develop carpal tunnel." *Id*. at 116. He describes Arcade of Frohse as "an anatomical structure under which the radial nerve passes as it branches into the superficial and the deep, and it branches, and the median nerve also goes underneath it." *Id*.

[18] Goebel A. Complex regional pain syndrome in adults. RHEUMATOLOGY 2011; 50: 1739-50. (filed as Ex. 56; hereinafter referred to as Ex. 56).

[19] The Budapest criteria require that the temperature asymmetry, if noticed by the physician, be greater than 1 degree Celsius. Ex. 56 at 3 ("If you notice temperature asymmetry: must be > 1°C"). Dr. Aradillas testified that his general practice is to refer his patients to another physician for temperature measurement because he does not have a thermometer in his office. Tr. at 49.

[20] On November 25, 2014, Petitioner underwent QST testing at Drexel University. QST is defined as "the determination of thresholds or stimulus response curves for sensory processing under normal and

She also had erythema (redness) of both shoulders in the supraclavicular fossa, purplish discoloration of both hands. *Id.* Regarding the sudomotor/edema category, Petitioner had swelling on the right arm and swelling of both hands (worse on the left hand). *Id.* Regarding the motor/trophic category, Dr. Aradillas noticed she had decreased strength on her right upper extremity in comparison to her left, and she had decreased facilitation of fine motor movements on both upper extremities. *Id.* at 119. Dr. Aradillas stated that he "basically found one of each categories -- or one of -- one sign in each of the categories for -- to fulfill the criteria for CRPS." *Id.*

3. Dr. Aradillas' Presentation of Petitioner's Pre-Vaccination Medical History

Dr. Aradillas highlighted the importance of Petitioner's pre-vaccination medical history in order to support Petitioner's diagnosis of CRPS. He appeared to do this for two reasons: (1) the Budapest criteria requirement that "[n]o other diagnosis can better explain the signs and symptoms" (*see* Ex. 56 at 3) is satisfied, in Dr. Aradillas' opinion, because he believes that Petitioner does not have fibromyalgia; and (2) her medical history shows that her prior pain amplified post-vaccination, which according to him, is a characteristic of CRPS pain.

On January 4, 2000, Petitioner was seen in the ER due to her motor vehicle accident (Ex. 10 at 81), and Dr. Aradillas explained that her accident caused her to suffer a whiplash injury, which usually injures the brachial plexus. Tr. at 98. Dr. Aradillas described the brachial plexus as branches of a tree, stating, "nerves are like trees in the literal sense, because when they come out of the spine, we call them nerve roots, and then these roots, they come together and form a trunk" and "whenever this tree is supposed to go, it branchs [sic]. We don't call them trees, we call them plexus." *Id.* Dr. Aradillas opined that, based on Petitioner's whiplash injury, she injured her left and right brachial plexus. *Id.* at 99-100. He further opined that her neck spasms that radiated to both of her hands suggest a brachial plexus injury. *Id.* at 100. He also noted that her pain was intermittent, which is not characteristic of CRPS. Petitioner's records from January 4, 2000 also note her neck pain radiating to her arm and her having radiculopathy. *See* Ex. 10 at 73. Dr. Aradillas posits that she did not have CRPS at this time because her pain was simply radiating down her arm; there was no central sensitization at this time because she did not have amplified pain. *Id.* at 101. Petitioner reported that her pain was relieved by nothing, which suggests to Dr. Aradillas that her pain was orthopedic in nature. *Id.*

On July 14, 2000, Petitioner had a right radial sensory nerve compression of the forearm Ex. 15 at 16. Dr. Aradillas testified that she developed pain in the distribution of the radial nerve

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pathological conditions." Uddin Z, MacDermid JC. Quantitative Sensory Testing in Chronic Musculoskeletal Pain. PAIN MED 2016; 17: 1694-703 (filed as Ex. 111; hereinafter referred to as Ex. 111). QST is considered semi-subjective. *Id.* at 1. It assesses subjective responses to a controlled stimulus. *Id.* The results for the hands and forearms indicated "evidence of mild cold thermal (A^{δ} fiber mediated) sensory deficit in the right hypothenar, and mild warm thermal (C fiber mediated) sensory deficits in the hypothenar bilaterally. Evidence of cold allodynia bilaterally." Ex. 36 at 47. The results for the feet indicated normal sensory detection thresholds. Further, that "[c]utaneous temperatures were warm with asymmetries in toes II-IV, right warmer than left." *Id.* This finding of temperature asymmetry and loss of sensation to cold is consistent with Dr. Aradillas' physical exam that he performed on October 13, 2014.

from her brachial plexus injury that was caused by her motor vehicle accident. Tr. at 102. He stated that her doctors found compression between the brachial radialis and extensor carpi radialis tendons (in the forearm – elbow downward). *Id*.

Dr. Aradillas attributed Petitioner's left and right carpal tunnel syndrome in 2001 to her motor vehicle accident because brachial plexus injuries can put one at risk to develop carpal tunnel. *See* Ex. 15 at 70 (Petitioner's right carpal tunnel release procedure); Ex. 15 at 46 (Petitioner's left carpal tunnel release procedure). Dr. Aradillas testified that there is no indication Petitioner had CRPS at this point in time. Tr. at 103-05.

According to Dr. Aradillas, Petitioner's mid and lower back pain in 2005 can be attributed to the abnormalities found in her spine; in other words, her MRI findings clinically correlated with the pain she was experiencing. *See* Ex. 123 at 49, 50 (MRI findings of thoracic spine and lumbosacral spine). *See also* Tr. at 109-10.

Dr. Aradillas discussed Petitioner's June 15, 2006 visit, when she had a nerve conduction study that resulted in a diagnosis of pancreatitis (Ex. 18 at 29); he testified that pancreatitis is an inflammation process that can trigger the exacerbation of chronic pain. Tr. at 106.

Petitioner had abdominal pain in 2008, which Dr. Aradillas attributed to her increased intake of Advil. Tr. at 111. She was taking more Advil due to her backaches, and Dr. Aradillas testified that Advil is known to cause gastritis and the exacerbation thereof. *Id. See also* Ex. 19 at 7 (Petitioner had a gastroenterology consultation for abdominal pain and notes she was taking more Advil); Ex. 19 at 5 (Petitioner had a follow up appointment for her abdominal pain for her chronic gastritis).

According to Dr. Aradillas, Petitioner's MRI of the thoracic spine on October 4, 2009 also clinically correlated with the intermittent pain she was experiencing. *See* Ex. 125 at 209. Dr. Aradillas believes that these MRI findings explain Petitioner's chronic back pain and that there was no indication of the central sensitization process. Tr. at 95.

Petitioner was admitted to Northwest Hospital Center for abdominal pain in March 2010 (Ex. 11 at 214-15), and Dr. Aradillas stated that her abdominal pain had the same characteristics as her prior abdominal pain in 2008. Tr. at 112-13. Her discharge summary, dated March 31, 2010, noted that she had gallstones. Ex. 11 at 204. Dr. Aradillas testified that Petitioner's abdominal pain resolved once treaters removed her gallbladder. Tr. at 113.

4. Fibromyalgia

Dr. Aradillas testified that Petitioner was incorrectly diagnosed with fibromyalgia in 2006. He is uncertain who diagnosed her and what criteria were used in order to make such a diagnosis. He stated that the diagnostic criteria for fibromyalgia were developed in 2010[21] (*see* Ex. 71 at 8

[21] Wolfe F, et al. The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity. ARTHRITIS CARE RES 2010; 62(5): 600-10 (filed as Ex. 71; hereinafter referred to as Ex. 71).

(the diagnostic criteria for fibromyalgia are satisfied when the following three conditions are met: (1) widespread pain index of greater than or equal to 7 and symptom severity scale score of greater than or equal to 5, or widespread pain index of 3 to 6 and symptom severity scale score of greater than or equal to 9; (2) symptoms were present at a similar level for at least three months; and (3) the "patient does not have a disorder that would otherwise explain the pain.")). Dr. Aradillas points out that Petitioner had no indication of any other symptomatology than in her arms. Tr. at 107. Furthermore, Dr. Aradillas opined that Petitioner could not have fibromyalgia because in his view, Petitioner's medical history provides an explanation for her pain.

5. Dr. Aradillas' Causation Theory

Prior to explaining Petitioner's medical theory in this case, Dr. Aradillas provided detailed information regarding pain and the communication of pain. Pain can be either neuropathic (injury to the nervous system), somatic (non-injury to the nervous system), or nociceptive[22] (A delta fiber or C fiber). Tr. at 63-65. Pain is communicated by way of the presynaptic neuron to the postsynaptic neuron, and there are also immune cells living in the central nervous system ("CNS"), which are known as astrocytes and microglia. *Id.* at 67. Astrocytes regulate the amount of neurotransmitters, specifically glutamate. *Id.* at 68. The effect on postsynaptic neurons will depend on the activation of these immune cells. *Id*. Once pain is communicated up the spinal cord to the brain, the process of stopping the communication of pain involves transmitting the release of inhibitory neurotransmitters in the synapse from the brain down to the spinal cord (descending nociceptive inhibitory control system). *Id.* at 70-71.

A process known as "central sensitization" occurs when the inhibitory neurotransmitters malfunction, thus resulting in an inability to turn off pain signals. Tr. at 71. Central sensitization[23] is a process that leads to the development of CRPS.[24] The main mechanisms involved in central sensitization, which must occur together, are the neuronal mechanism and the immune cell mechanism (regarding the immune cells that surround neurons). *Id.* at 60, 76.

a. Prong 1

Dr. Aradillas' medical theory in this case was stated as follows:

> the [flu] vaccine caused the normal activation of the innate system, causing increasing inflammatory cytokines to circulate, plus the vaccine also caused an

[22] Nociceptors can be activated by mechanical stimulus (noxious stimulus) or by the immune system.

[23] According to Dr. Low, central sensitization is a process that creates many chronic pain syndromes, including the development of CRPS. Dr. Low states, "…all we heard about is maybe the previous pain that she had took on different characteristics….You were shown…slides about pathways, amplification, and central sensitization. First of all, that's not specific to CRPS. That occurs in neuropathies, it occurs in other conditions, so it really does not mean much." Tr. at 191-92.

[24] CRPS divides into two subtypes, Type I and Type II. If an individual has a nerve injury, his or her CRPS is classified as Type II. Tr. at 43-44.

> allergic reaction, causing the degranulation of mast cells, which both together caused the permanent activation of microglia and astrocytes, glial cells surrounding the synapse of the pain transmission neurons, which led to this permanent glutamate-dependent neuroplasticity or central sensitization syndrome and manifested clinically as a worsening of her or amplified her old pains and the development of complex regional pain syndrome.

Tr. at 131.

Dr. Aradillas testified that a noxious event, traumatic or non-traumatic, can cause CRPS. Tr. at 152. In his experience, 60% of his patients experienced a traumatic event (i.e., fracture, torn limb, and amputation) and 40% of his patients experienced a non-traumatic event (i.e., needle stick, blood work, IV placement, and walking on an extremely cold surface). Tr. at 152-53. Despite such causes, Dr. Aradillas is of the opinion that "the vaccine triggered the central sensitization syndrome…which amplified her old pains. Rather than the needle stick itself." Tr. at 154-55. Dr. Aradillas does not "believe that the vaccine caused a local injury[;]" he believes "that the vaccine triggered her immune system to react in an allergic way, which triggered the central sensitization, [which] triggered her [] amplified pain on the region where she [] had chronic pain." Tr. at 155. Dr. Aradillas explained that her region of pain was the exacerbation of her old pain rather than from pain at the initial site because, in his opinion, there was no noxious event that caused her to have CRPS. Rather, an autoimmune response amplified and created a spread of her old pain. Tr. at 142 (explaining that Petitioner's region of pain was in "her left buttock, right buttock, all the way down to the knees…bilaterally" and that "pain doesn't need to start where the injury starts").

b. Prong 2

Dr. Aradillas concludes that the flu vaccination stimulated Petitioner's immune system, which triggered her CRPS. Tr. at 86. Such activation occurred by her allergic reaction to the flu vaccine and the vaccine itself–both resulted in the activation of her immune system. *Id.*

Using the Budapest Criteria as a framework, Dr. Aradillas opined that Petitioner met each of the four criteria. Dr. Aradillas referenced Petitioner's medical records to support the fact that Ms. Dixon-Jones had been experiencing continuing pain during the 2012 timeframe. Aradillas Rep. at 6. In support of the second criterion, Dr. Aradillas stated that Petitioner has reported both hyperesthesia and allodynia to her doctors. Further, his exam of Petitioner revealed that she had swelling of the left supraclavicular fossa, erythema, and obvious livedo reticularis all throughout the upper extremities. She also had erythema and diaphoresis, especially at the hands. Finally, Dr. Aradillas observed some dystrophic changes on the fingernails. *Id.* at 13-14.

Dr. Aradillas highlighted medical events subsequent to Petitioner's October 6, 2011 vaccination that reflect the initiation of the central sensitization process that developed into CRPS. Petitioner had an allergic reaction to the flu vaccine, which is noted on October 12, 2011. Ex. 26 at 27. Dr. Aradillas notes that her allergic reaction was her first initial pain as well as the activation of her immune system. In support of his assertion, Dr. Aradillas references a study that measured

the production of inflammatory cytokines in participants who received flu vaccine.[25] The study explained how flu vaccine can stimulate the innate immune system, and Dr. Aradillas noted that the results from the study revealed "that the production of tumor necrosis factor alpha and interleukin 6 after a vaccination is associated with antibody response to the influenza vaccine[.]" Tr. at 88.

He opines that her abdominal pain on October 23, 2011 (Ex. 11 at 8) was indicative of the central sensitization process. Four weeks after her vaccination, on November 4, 2011, Petitioner reported ear pain that worsened when touched. Ex. 20 at 4. Dr. Aradillas explains her ear pain was allodynia (an experience of pain from a non-painful stimulus). He opines that the central sensitization process was beginning to occur.

Petitioner's abdominal and back pain, described as a burning and band-like pain, on November 8, 2011 is, in Dr. Aradillas' opinion, indicative of the central sensitization process because her old pains were being amplified. Tr. at 126-29. He explains that her pain had a new description of being bilateral in her upper abdomen and chest, and that her burning sensation was a neuropathic feature. *Id.* at 130.

Dr. Aradillas points out that her pain on December 9, 2011 (Ex. 16 at 23) was indicative of the central sensitization process occurring as well as CRPS. He explains that Petitioner's old pain was only in her low back as reflected in a diagram (*see* Ex. 13 at 38), while her new pain is low back pain that radiates down to her right and left knees, her left and right buttocks.[26] She also had muscle stiffness and described her pain as burning, aching, and constant. In his opinion, her old pain was amplified, which is characteristic of the central sensitization process and CRPS. He also noted that she was showing motor symptoms and having constant, not intermittent, pain, which is indicative of CRPS. Dr. Aradillas explains that Doppler tests are usually conducted for leg swelling, which Petitioner underwent on February 2, 2012 (Ex. 11 at 48). Tr. at 130.

Dr. Aradillas is of the opinion that Petitioner met the diagnostic criteria for a CRPS diagnosis on February 6, 2012.

c. Prong 3

Dr. Aradillas believes that CRPS began at a temporally appropriate time with respect to Petitioner's flu vaccination, pointing out that onset of her symptoms was on November 4, 2011, four weeks after vaccination. Tr. at 137 (stating that "pain in her face" was the first symptom of CRPS). On such date, she reported ear pain that worsened when touched, which, according to Dr. Aradillas was allodynia and an indication that her central sensitization process began.

B. Dr. Phillip Low

[25] Mohanty S, et al. Prolonged Proinflammatory Cytokine Production in Monocytes Modulated by Interleukin 10 After Influenza Vaccination in Older Adults. J INFECT DIS 2015; 211: 1174-84 (filed as Ex. 105; hereinafter referred to as Ex. 105).

[26] As discussed infra, this is not an accurate summary of the medical records.

Dr. Low offered a single expert report in this case and testified at the hearing. *See* Expert Report, dated March 21, 2016, filed as Ex. A (ECF No. 33-1); Tr. at 162-221.

Dr. Low received his medical and research doctorate degrees from the University of Sydney in Sydney, Australia. *See* Low CV, filed as Ex. B (ECF No. 33-2) ("Low CV"). Following graduation, Dr. Low completed a fellowship in internal medicine with the Royal Australian College of Physicians. Low CV at 2. Currently, Dr. Low serves as Professor of Neurology at the Mayo Clinic Medical School. Low CV at 4.

During his time with the Mayo Clinic, Dr. Low served in various departmental and academic capacities, including Director of the Neuroscience Laboratory, Director of the Autonomic Reflex Laboratory, and Chairman of the Division of Clinical Neurophysiology. Low CV at 3-4. At Mayo, he founded the autonomic reflex lab. Tr. at 164. Dr. Low has co-authored over 400 items of literature in the field of autoimmunity, including the largest series of publications centered on antibody-mediated autoimmune neuropathies. *Id*. at 167; *see also* Ex. B at 9-50. Dr. Low has also served on the editorial boards of multiple journals centered on autonomic and nervous system research, including the *Journal of Clinical Neurophysiology*. Low CV at 5. He also consistently serves as a research advisor to postdoctoral fellows at the Mayo Clinic Medical School. *Id*. at 7-9.

Over the course of his career, Dr. Low's time has been divided between patient practice and research. Tr. at 165. Dr. Low's clinical practice is focused on autonomic disorders, including work heading clinical trials on autonomic disorders and drug trials. *Id.* Dr. Low sees about 10 patients per week for CRPS; however, "the numbers that have turned out to be positive are far less."[27] *Id.* Dr. Low has served as a reviewer in peer-reviewed medical journals, such as New England Journal of Medicine, Lancet, Neurology, and the British Medical Journal. *Id.* at 168. I recognized Dr. Low as an expert in neurology. Dr. Low was highly qualified to provide expert testimony in this case.

Dr. Low does not believe that Petitioner has CRPS and disagrees that Dr. Aradillas correctly diagnosed her with CRPS. Dr. Low bases his conclusion on the medical records, which he states do not support this diagnosis. *See generally* Tr. at 162-221.

1. Budapest Criteria: Weaknesses and Objective Measurements

[27] Dr. Low testified that he treats patients with CRPS; however, he declined to provide exact details on how he treats his patients. Dr. Low expressed that he does not conduct IVIG treatments for his patients with CRPS, describing such treatment as ineffective. Tr. at 198. *See also* Tr. at 205 ("I don't use ketamine infusions, and I don't use IVIg"); Goebel A, et al. Low-Dose Intravenous Immunoglobulin Treatment for Long-Standing Complex Regional Pain Syndrome. ANN INTERN MED 2017; 167(7): 476-83 (filed as Ex. K; hereinafter referred to as Ex. K) ("Low-dose immunoglobulin treatment for 6 weeks was not effective in relieving pain in patients with moderate to severe CRPS of 1 to 5 years' duration").

Dr. Low described CRPS as a rare disease, with an incidence of five per 100,000. Tr. at 165, 176. He explained that the Budapest Criteria[28] are the diagnostic standard; however, these criteria have limitations in that they very much depend on the clinician who makes the diagnosis. *Id.* at 217. Dr. Low explained that the weakness of the Budapest Criteria is that the "interpretation of the signs doesn't specify a quantitative aspect…but a quantitative aspect is understood, so that it's understood that the clinician…should not say that this arm is warmer or colder unless…it really is at least a degree, and in terms of sweatiness, unless it's obvious." *Id.* While the Budapest Criteria do not detail how signs should be measured, Dr. Low has a "significant" measurement approach. *Id.* at 215. For example, regarding color and sweat changes, Dr. Low noted that such changes do not "need to be extreme, but it has to be significant, and by 'significant' we require a 50 percent difference between sides." *Id.* Further detailing his approach in regard to the symptomalogical asymmetry requirement for the Budapest Criteria, Dr. Low stated that it could be in the upper or lower extremity, and he looks at three things. *Id.* at 212-13. Regarding temperature distribution, "[y]ou might take a thermogram of the upper extremity, and you look at the distribution of temperatures." *Id.* at 213. Regarding sweating, "we would use a larger capsule that would measure resting sweat activity over the two extremities simultaneously over a defined period of time." *Id.* "And then, thirdly, we would do the QSART[29] measurement at two different levels to -- and also do that simultaneously." *Id.* The way in which Dr. Low's laboratory objectively documents the signs is by comparing two limbs, "the affected and non[-]affected, side by side to measure how much sweating differential there is, and then you could document temperature. You could use a thermogram, for instance, and look at the pattern of sweat -- of temperature difference, and it's quite characteristic when we do that." *Id.* at 174.

2. Characteristics of CRPS

Dr. Low, citing medical literature, defined CRPS as "characterized by a continuing (spontaneous and/or evoked) regional pain" and as "pain [which] is regional…and usually has a distal predominance of abnormal sensory, motor, sudomotor, vasomotor, and/or trophic findings."[30] Tr. at 171. Dr. Low emphasized that although patients with CRPS can have different levels of pain, the condition is characterized by regional pain, meaning that "it's outside of the distribution of one or more peripheral nerves. It's usually in a region of the body, such as an arm or a leg, and the appearance is fairly characteristic." *Id.* Dr. Low testified that CRPS pain does

[28] The Budapest Criteria evolved as a remedy to the International Association for the Study of Pain (IASP) criteria's limitations, which were dependent solely on what the patient reported to the physician. Tr. at 172. Due to the need to have both symptoms and signs, the Budapest Criteria were developed; Dr. Low points out "they recognized that the Budapest criteria had one weakness, and that is it depended solely on what the physician found. They recognized that -- and actually, it does specify [ ] that you needed at least one degree Celsius in temperature difference." *Id.* at 173. Dr. Low "emphasized it was really necessary to document how much sweat difference between the two limbs and how much temperature difference there was." *Id*.

[29] Dr. Low notes that QSART is not a part of the Budapest Criteria, as it was made "very clear that it had to be what's available to the clinicians who practiced at different levels, at different places." Tr. at 212.

[30] Harden RN, Bruehl S. Proposed New Diagnostic Criteria for Complex Regional Pain Syndrome. PAIN MED 2007; 8(4): 326-31 (filed as Ex. C; hereinafter referred to as Ex. C).

spread over time, but when that happens, the patient retains an asymmetry; in other words, if a CRPS patient has one affected limb, that limb will still be impacted after spread. *Id.* at 175. The pain in the initial region does not change much and will not subside unless the condition is improved. *Id.* Further, Dr. Low agrees that medical literature supports that one can experience initial pain in a region that is different from where the patient received his or her needle stick. *Id.* at 219.

Dr. Low further testified that CRPS results in unrelenting pain that is without remission. The pain "simply doesn't change."[31] Tr. at 171. For example, a "patient isn't going to come in and see one physician and have a normal exam and the next day have severe abnormalities as noted by someone else." *Id.* at 172. Dr. Low expressed that allodynia and hyperalgesia (increased sensitivity to pain) were "well described" by Dr. Aradillas, "but there also [are] prominent autonomic manifestations, manifest[ed] as color changes, as swelling, and as sweating, and also by trophic changes that affect bone, nail, soft tissue, et cetera. It almost invariable -- some say invariably begins with a lim[b]." *Id.* at 171. Dr. Low testified that a typical presentation of CRPS is allodynia, hyperalgesia, and prominent trophic changes.[32] *Id.* at 173. Further, "[i]t will usually be a limb….You just cannot put the capsule on their skin. They don't want you to touch them because of the allodynia and hyperalgesia, and they also have trophic changes that could be quite problematic." *Id.* CRPS does not wax and wane, and diffuse body pain is not a characteristic of CRPS.[33] Fibromyalgia, however, does wax and wane and patients "get periods of improvement and periods of worsening." *Id.* at 175. Petitioner's remission of pain suggests that she has fibromyalgia or chronic pain.

3. Petitioner's Medical Records

As noted, the Budapest Criteria require signs and symptoms. In order to make a CRPS diagnosis in his patients, Dr. Low looks for signs such as changes affecting a region, not one site, "where there would be a temperature change and a significant temperature change, a color change….swelling, and…trophic changes." Tr. at 190-91. Dr. Low emphasized the importance of quantifiable signs. Regarding symptoms, Dr. Low looks for unrelenting pain with allodynia

[31] During cross-examination, Dr. Low, was provided with the following quote: "CRPS symptoms vary in severity and duration, although some cases are mild and eventually go away. In more severe cases, individuals may not recover and may have long-term disability." Tr. at 220 (citing National Institutes of Health, Complex Regional Pain Syndrome Fact Sheet (2019), https://www.ninds.nih.gov/disorders/patient-caregiver-education/fact-sheets/complex-regional-pain-syndrome-fact-sheet (filed as Ex. 94; hereinafter referred to as Ex. 94)). Dr. Low clarified that such a quote "refers to patients who recover….[Y]ou could have terrible disease, stay steady, what I'm referring to, one two, three, four weeks, and then the patient gets better. That can occur, but during the time that you have that monophasic illness, your symptoms are relatively stable." Tr. at 220-21.

[32] "Trophic changes could be trophic changes to hair. It could fall off or it could be fairly thick; could be thickening of skin. There's obviously swelling, and the nails could grow excessively, and the bone changes are actually very characteristic." Tr. at 173.

[33] Dr. Low explains that diffuse body pain occurs "in many conditions, many painful conditions. It occurs in the neuropathies, et cetera, but…it's not specific to CRPS." Tr. at 176.

and hyperalgesia. *Id.* at 191. Dr. Low often sees such symptoms in a patient who is requesting not to be touched due to pain. *Id.* Dr. Low states that he does not believe that Petitioner's clinical course is CRPS that has spread as he does not "get a picture of when it began" and he does not "have a picture of…sufficient severity, the combination of pain and autonomic findings[,]" which Dr. Low likes to see before looking at spread. *Id.*

During his testimony, Dr. Low highlighted Petitioner's medical records shortly after her receipt of flu vaccine. He acknowledged that Petitioner had a brief reaction to flu vaccine that resolved. *See* Ex. 132 at 1 (On October 10, 2011 "patient states that she had a flu shot about a week or two ago and had a reaction to the flu shot; however, that has resolved"); Ex. 26 at 27 (On October 12, 2011 "skin is clear….no hives….area of the injection on the right arm is not visible").

Dr. Low noted that on January 9, 2012, Petitioner's lower back pain remained unchanged and that her LESI helped with her low blood pressure. *See* Ex. 29-33. He explained that her continued generalized muscle weakness, fatigue, and dizziness that she experienced were not characteristics of CRPS. Tr. at 182. According to Dr. Low, her diffuse pain noted on February 17, 2012, is from fibromyalgia and not CRPS.[34] *See* Ex. 18 at 7 (Petitioner "complained that she was having diffuse pain throughout her entire body from her fibromyalgia"). Dr. Low stated that symptoms of tingling could be neuropathic symptoms, which is a characteristic of CRPS II; however, this was not the case with Petitioner on her May 7, 2012 visit.[35] *See* Ex. 16 at 49. Dr. Low believes that occasional tingling and piercing sensations in random areas are not characteristics of CRPS; rather, he thinks "those are common symptoms seen in fibromyalgia." Tr. at 183.

Dr. Low saw no signs of CRPS documented by Dr. Kozachuk on June 14, 2012. Tr. at 184. Petitioner had sensory examination of the hands, which were normal to touch; she had no pain to palpation, and motor exam of the arms was normal. *See* Ex. 24 at 3. Dr. Low reviewed Dr. Kozachuk's neurologic examination of Petitioner on July 25, 2012 where Dr. Kozachuck conducted a motor, sensory, reflex, and gait examination. Tr. at 184-85; *see also* Ex. 24 at 5-8. The exam indicated no pain palpations and normal motor exam of the arms, but abnormal neurologic exam with increased reflexes in the legs with spread and body myoclonic jerks. Tr. at 184-85.

Dr. Low testified that on June 17, 2013, Dr. Williams' examination of Petitioner revealed normal color and temperature under the categories "left and right vascular." Ex. 127 at 33. "[T]hey're just looking at the color. Vascular on the right side, normal color and temperature. So there's no changes in color or that examination….[I]t certainly shows no signs of CRPS." Tr. at 188. On August 21, 2014, Dr. Williams, according to Dr. Low, "looked carefully on the thorax, and certainly no erythema, no swelling, normal temperature. Yeah, normal examination, apart from

[34] Dr. Low thinks "that diffuse pain with trigger points is much more consistent with fibromyalgia than CRPS." Tr. at 183.

[35] "…the fact that someone has tingling, paresthesias, doesn't necessarily mean they actually have neuropathy. There are symptoms obviously coming from nerves, but patients have nerve-type symptoms for lots of reasons." Tr. at 184.

his interest in radial neuropathy, as he calls it." *Id.* at 189; *see also* Ex. 127 at 15-19. Dr. Low was asked whether Dr. Williams' examination was one that would reveal signs of CRPS to a doctor like Dr. Williams if such signs were present, and Dr. Low responded, "In fact, this is a very good -- unusually good examination because of the great interest in minor findings, so that they do a very careful examination for color, for swelling, et cetera, and there was no evidence of anything for CRPS." Tr. at 189.

4. Dr. Aradillas' Examination and Diagnosis

Dr. Low discussed Dr. Aradillas' examination of Petitioner on October 13, 2014. Tr. at 189; *see also* Ex. 23 at 6. Dr. Low testified that he would not have diagnosed Petitioner with CRPS based on the clinical findings because,

> …quantitatively, the changes are very modest. In terms of the color changes, I would look for more -- I would like to quantitate the severity; I would like to quantity the difference. As far as the hands are concerned, if you shook hands with a bunch of people, in normal people, you often find a little bit of moisture. I don't think it means any – you cannot make a diagnosis of CRPS based on that.

Tr. at 190. Dr. Low also would not have diagnosed Petitioner with CRPS based on Dr. Aradillas' findings of CRPS signs on May 29, 2015. *Id.*; *see also* Ex. 125 at 36-39. Dr. Low testified that he looks for "changes not at one site, but affecting a region, where there would be a temperature change and a significant temperature change, a color change…swelling, and…for trophic changes." Tr. at 190-91.

5. Petitioner's Bone Scan Results

On March 28, 2013, Dr. Nasseri conducted a bone scan of Petitioner to rule out CRPS. Ex. 11 at 41. The exam was normal. *Id.* Dr. Low testified that this normal result further supports his opinion that Petitioner does not have CRPS. Dr. Low testified that while normal bone scans do not exclude CRPS, normal results reveal that CRPS is significantly less likely to be present.[36] Tr. at 194. To further support his position, Dr. Low referenced an article based on an epidemiologic study that was conducted under his guidance.[37] "We found that the bone scan sensitivity was

[36] Dr. Low testified that "the reason why it hasn't been adopted as a gold standard is because different laboratories do it -- they have some difficulty agreeing, what exactly is normal, where is the cutoff, normal and abnormal." Tr. at 193; *see also* Wertli MM, et al. Usefulness of bone scintigraphy for the diagnosis of Complex Regional Pain Syndrome 1: A systemic review and Bayesian meta-analysis. PLOS ONE 2017; 12(3): e0173688 (filed as Ex. 102; hereinafter referred to as Ex. 102)(meta-analysis of bone scans).

[37] The article states that "[t]hree-phase bone scan was done in 34/74 (46%) cases. In 29/34 (85%), the scan showed a pattern consistent with the diagnosis of CRPS. Autonomic testing was done in 40/70 (54%) and detected asymmetry in sympathetic function in 32/40 (80%)." Sandroni P, et al. Complex regional pain syndrome type I: incidence and prevalence in Olmsted county, a population-based study. PAIN 2003; 103: 199-207 (filed as Ex. F; hereinafter referred to as Ex. F).

actually quite good, with about 85 percent of patients ha[ving] an abnormal bone scan, and about the same percent of patients ha[ving] abnormal autonomic function tests." *Id.* at 192. Dr. Low made the point that the data revealed "a sensitivity and specificity of over 80 percent." *Id.* at 193. In Dr. Low's opinion, the fact that Petitioner's bone scan results were normal is supportive of his opinion that she did not suffer from CRPS.

6. Fibromyalgia

Dr. Low also highlighted medical records in support of his opinion that Petitioner's correct diagnosis was fibromyalgia and not CRPS. He pointed out that there is no evidence of CRPS found on December 19, 2011, when Petitioner saw her neurologist, Dr. Sellman. *See* Ex. 18 at 15. Dr. Sellman noted that Petitioner had completely normal motor function. *See id*. The only abnormality found during that visit included her difficulties with tandem walking; however, Dr. Low does not place a lot of significance on this; he pointed out that often times people who are not ill have difficulty performing a heel-to-toe walk. Tr. at 181. Dr. Low also testified that Petitioner's neurologist noted she had baseline fibromyalgia pain in her arms.[38] *See* Ex. 18 at 16.

Dr. Low, referencing Petitioner's medical record dated February 14, 2013, pointed out that Petitioner "was diagnosed with fibromyalgia syndrome in 2006." *See* Ex. 3 at 6. Regarding Dr. Nasseri's examination, Dr. Low "thought his examination of the extremities was very careful, because he talks about looking at the skin, looking at the nail, and looking at muscle strength..." Tr. at 185. The doctor "also points out numerous tender points[39] to examination, but he was a rheumatologist, so he would specifically seek out tender points, because that is a characteristic of fibromyalgia." *Id.* Dr. Nasseri examined Petitioner's skin and nails, which revealed "no rash, no nail bed changes, no varicose veins." Ex. 3 at 6-7. The examination further revealed that Petitioner had "numberous [sic] tender points on trunk, and upper and lower extremities" and no other tender points found. *Id.* at 7. Dr. Low points out that examination of Petitioner's skin and nails were normal, and she did not have swelling. Dr. Low also emphasizes that on March 20, 2013, when Petitioner was again examined by Dr. Nasseri, the doctor "noted numerous tender points on trunk and upper and lower extremities; also noted, again, skin was fine, no nailbed changes, and normal strength. Then he makes his conclusion that she's got fibromyalgia that's quite troublesome." Tr. at 187; *see also* Ex. 125 at 137 (doctor noted, "I believe that the symptoms that she is describing are an exacerbation of her previously diagnosed fibromyalgia. I believe that her fibromyalgia is very severe.").

7. Causation

[38] According to Dr. Low, the medical record references a prior diagnosis of fibromyalgia. Tr. at 181. Dr. Sellman "mentions that her baseline -- that she has fibromyalgia and that she has some baseline and continuing fibromyalgia pain." Tr. at 181.

[39] Explaining the purpose of examining tender points, Dr. Low stated that a doctor asks the patient whether he or she has soreness in certain areas and the doctor will "press down on it to see whether it hurts or not. If someone did that to you, you might feel pressure but not pain, whereas with tender points, they feel it as pain, and the value is if they find that tender point, they could go and inject it." Tr. at 185-86.

Dr. Low opined that the cause of CRPS is unknown. Tr. at 218. In regard to the flu vaccine causing CRPS, Dr. Low testified that he "looked at all the literature that [he] could get his hands on in terms of flu shot and CRPS, and…most of the literature was on GBS, but in terms of CRPS, there was virtually nothing." Tr. at 194. Regarding Dr. Aradillas' theory, Dr. Low stated that Dr. Aradillas described "changes that you see at the local area, changes that you see at the brain. In fact, the changes that he described occur in many painful neuropathies….This process of central augmentation, of central sensitization…applies to many conditions." Tr. at 218. Dr. Low also testified that anyone who experiences pain can have "some autonomic fluctuations, because the autonomic nervous system is invariably affected when [one has] pain, so that there is some change in control of the blood vessels and some change in control of sweating, but that doesn't make it CRPS." Tr. at 218.

In regard to a needle prick causing CRPS, Dr. Low testified that "CRPS has been well described after needle." Tr. at 195. He explained that a common trigger is a fracture as well as surgery, but ultimately CRPS "has been described after needle as well." *Id.* Dr. Low, however, does not see evidence of Petitioner's flu shot needle stick triggering CRPS. *Id.*

Dr. Low testified that "if a vaccine did cause CRPS" then the condition is expected "to develop rapidly, certainly within two months, probably within a month, that it would reach a peak fairly quickly, and so linkage by time is critically important."[40] Tr. at 194.

In summary, Dr. Low believes that Petitioner does not have CRPS; rather, she has a chronic pain disorder with fibromyalgia and chronic fatigue. Tr. at 220. Dr. Low, applying the Budapest Criteria along with his objective diagnostic approach, made this conclusion after reviewing Petitioner's medical records, with close attention to the signs observed by Petitioner's treating physicians. Dr. Low also found it noteworthy that Petitioner had a prior history of chronic pain and fibromyalgia and points out that none of Petitioner's treating physicians post-vaccination diagnosed her with CRPS until her diagnosis made by Dr. Aradillas, which occurred three years after her vaccination.[41]

V. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

[40] During cross examination, Dr. Low was asked whether CRPS would manifest itself to satisfy the Budapest Criteria within a week or so after a noxious event (vaccine administration), to which Dr. Low answered it is "[h]ard to say" which is why he provided manifestation occurs "within two months, because sometimes it does take a while to evolve. In fact, following a noxious event, everything in the literature says that it should occur within two months, usually within a month." Tr. at 214.

[41] "Between [Dr. Aradillas'] examination and the vaccination, [Petitioner] had been seen by numerous physicians….who should be expert[s] at either the neurological exam or with pain, and these are people who have examined her a number of times and who state in their notes that her arms had normal temperature, normal appearance, no pain, and motor function." Tr. at 117. Dr. Low highlights "superb" examinations of Petitioner conducted by Dr. Nasseri, "who not only looked at her limbs carefully," but also defined trigger points, which is characteristic of fibromyalgia, and had been injecting her trigger points. Tr. at 177.

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination he received caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must be only "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens

of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds,* 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs*., No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem*., 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human*

Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs*., 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *mot. for review den'd* (Fed. Cl. Feb. 11, 2019), *appeal docketed*, No. 19-1753 (Fed. Cir. 2019); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have

been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, Petitioner's claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that she suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. CRPS Generally

CRPS is "a severe chronic pain condition characterized by sensory, autonomic, motor and

dystrophic signs and symptoms."[42] Specifically, the signs and symptoms of CRPS involve four main categories: (1) abnormalities in pain processing that can include allodynia, where a non-painful stimulus is perceived as painful, and hyperalgesia, an enhanced pain response; (2) vasomotor symptoms which can involve skin color changes or asymmetry and/or temperature asymmetry between the extremities; (3) swelling, and changes/asymmetry in sweat function; and (4) motor dysfunction which can include weakness, reduced range of motion, and tremor, and trophic changes that may affect bone, nail, hair, and skin. Ex. 39 at 7. Although the cause of CRPS is unknown, it typically develops after some type of trauma to a limb.[43] This trauma typically involves surgeries, fractures, crush injuries, and sprains.[44] It can, however, develop after a minor injury, and has been reported after needle stick.[45,46,47,48]

Ninety-two percent of CRPS patients reported that their pain spread to other areas of their body from where it originally started.[49] Contiguous spread was most common early in the course of the disease (1-2 years) whereas spread to all extremities was most often seen after 15 years. *Id.* In terms of the quality of the pain: "The pain in CRPS is continuous, it worsens over time, and is usually disproportionate to the severity and duration of the inciting event." Ex. 43 at 1.

B. The Expert Testimony

I have evaluated the opinions of both experts in this case and find that Dr. Low's testimony was the more persuasive of the two. Both experts were qualified to testify about CRPS, and in fact, Dr. Aradillas was offered and qualified as an expert specifically in the field of CRPS.

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[42] Alexander GM, et al. Changes in immune and glial markers in the CSF of patients with Complex Regional Pain Syndrome. BRAIN BEHAV IMMUN 2007; 21: 668-76 (filed as Ex. 43; hereinafter referred to as Ex. 43).

[43] Goebel A. Complex regional pain syndrome in adults. RHEUMATOLOGY 2011; 50: 1739-50 (filed as Ex. 56; hereinafter referred to as Ex. 56).

[44] Bruehl S. An Update on the Pathophysiology of Complex Regional Pain Syndrome. ANESTHESIOLOGY 2010; 113(3): 713-25 (filed as Ex. 55; hereinafter referred to as Ex. 55).

[45] Bilić E, et al. Complex Regional Pain Syndrome Type I after Diphtheria-Tetanus (Di-Te) Vaccination. COLL ANTROPOL 2013; 37(3): 1015-18 (filed as Ex. 58; hereinafter referred to as Ex. 58).

[46] Kwun BS, et al. Complex regional pain syndrome by vaccination: A case of complex regional pain syndrome after vaccination of influenza A(H1N1). PEDIATR INT 2012; 54: e4-e6 (filed as Ex. 59; hereinafter referred to as Ex. 59).

[47] Richards S, et al. Complex regional pain syndrome following immunization. ARCH DIS CHILD 2012; 97: 913-15 (filed as Ex. 60; hereinafter referred to as Ex. 60).

[48] Genc H, et al. Complex regional pain syndrome type-I after rubella vaccine. EUR J PAIN 2005; 9: 517-20 (filed as Ex. 62; hereinafter referred to as Ex. 62).

[49] Schwartzman RJ, Erwin KL, Alexander GM. The Natural History of Complex Regional Pain Syndrome. CLIN J PAIN 2009; 25(4): 273-80 (filed as Ex. 41; hereinafter referred to as Ex. 41).

However, during his testimony, Dr. Aradillas displayed apparent gaps in knowledge that undermined his overall opinion. There are several examples, below, from the hearing. At the beginning of cross examination, Respondent's counsel asked Dr. Aradillas a series of questions about Petitioner's initial signs[50] of CRPS:

> **Q:** What do you believe was the first objective sign of Ms. Dixon-Jones' CRPS?
>
> **A:** It was probably the allodynia that -- the pain she reported to touch later on on her face, a month later when she reported that she hurt to touch. That would be the first sign of CRPS, I would think.
>
> …
>
> **Q:** So, Doctor, will you take a second to refresh your recollection and show me where the objective sign that you're referencing is documented.
>
> **A:** It's here on the body of the history of present illness. The -- Ms. Dixon-Jones states that the pain was piercing, which was worsened if she touches anywhere around her ear.

Tr. at 137-38.

Eventually, Dr. Aradillas acknowledged there was no sign documented in the medical records of facial pain or ear pain. *See* Tr. at 139. Respondent's counsel continued with this line of questioning:

> **Q:** So at Exhibit 18, page 7, is Dr. Sellman's February 17th, 2017 [sic], notes of that visit on February 17, 2012, and where there do you see an objective sign of CRPS?
>
> **A:** Here, under the cranial function, the last paragraph, it says, "She complained that she was having diffuse pain throughout her entire body from her fibromyalgia."

Tr. at 141.

Although Dr. Aradillas did provide accurate definitions of symptoms and signs when asked to do so on cross examination and eventually testified that walking slowly and exhibiting decreased range of motion were signs, his repeated confusion of the difference between signs and symptoms caused me to give less weight to his testimony than to that of Dr. Low.

Dr. Aradillas also testified extensively about Petitioner's pre-CRPS medical history, and how he could distinguish between her pre-existing pain, and her pain associated with CRPS. Petitioner visited Harbor Pain Associates on October 14, 2009 and filled out a patient questionnaire. *See* Ex. 13 at 38. Harbor Pain Associates completed a new patient evaluation on

[50] A sign is defined as "an indication of the existence of something; any objective evidence of a disease, i.e., such evidence as is perceptible to the examining physician, as opposed to the subjective sensations (symptoms) of the patient." Dorland's at 1708.

October 16, 2009. *See* Ex. 13 at 32. Dr. Aradillas testified about both of these documents. He first discussed the new patient evaluation (Ex. 13 at 32).

> **Q:** How does this medical history help with your assessment of Ms. Dixon-Jones' diagnosis?
>
> **A:** Well, you can see here that it is the first time that she went to [a] pain doctor for her chronic pain. … Yes, this particular pain doctor. And she was only complaining of it seems like pain in the mid and low back, and she described it as an occasional burning sensation in the mid[-]back that radiates laterally on the right side, and she also says that she takes for it Lyrica at bedtime, as needed.

Tr. at 93.

He next discussed the significance of the questionnaire (Ex. 13 at 38):

> **Q:** So this is a patient questionnaire, and what can you learn from looking at Exhibit -- at page 38 here? This was filled out by Mrs. Dixon-Jones.
>
> **A:** Well, you can see that the only region in her body that she marked as painful was right down here is in the low back. She didn't mark anything on the -- going down the legs. She didn't mark anything on her arms. It was just basically restricted to the low back.

Tr. at 94.

Dr. Aradillas' summary of these two records is not complete. Further, his conclusion that Petitioner did not suffer any pain from her back that radiated to her legs in the 2009 timeframe is inaccurate. When he summarized the new patient evaluation in his testimony, Dr. Aradillas left out one key sentence. The relevant portion of that document reads as follows:

> She describes occasional burning sensation in the mid back area that radiates laterally on the right side. **She also describes an achy sensation in the low back that radiates into her right buttock as well as her right thigh.** She takes Excedrin PM as needed as well as Lyrica 75 mg at bedtime as needed.

Ex. 13 at 32 (emphasis added). In summarizing the record in his testimony, Dr. Aradillas left out the sentence bolded above. He testified to the sentence before and after but made no mention of pain radiating from the back to the buttock and thigh. *See* Tr. at 93. Then he went on to testify that Petitioner did not mention pain going into her legs in the questionnaire, leaving the impression that there was no pain radiating into her legs in 2009. This incomplete and inaccurate testimony concerning Petitioner's pre-vaccination medical history was an additional factor that caused me to place less weight on his testimony as compared to that of Dr. Low.

Finally, I found Dr. Low to be the more credentialed expert witness. He is a professor of neurology at the Mayo Clinic with a named chair. He has been board certified in neurology for

nearly 40 years, and during that time, has both seen patients and conducted research. In short, Dr. Low's testimony was extremely helpful to me in the resolution of this case and I gave it more weight than I did the testimony of Dr. Aradillas.

C. Petitioner has not Carried her Burden of Proof

1. There is not Preponderant Evidence that Petitioner Suffers from CRPS

The first step in an "off-Table" claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury," and "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *see Broekelschen*, 618 F.3d at 1346 (explaining that "identifying the injury is a prerequisite to the [causation] analysis"). In this case, Petitioner has not demonstrated that she suffered from CRPS.

In order to be diagnosed with CRPS, a patient must have continuing pain disproportionate to any inciting event, display the signs and symptoms enumerated in the Budapest Criteria, and establish that no other diagnosis better explains the patient's signs and symptoms. Dr. Low testified that he believes Petitioner was correctly diagnosed with fibromyalgia and that her fibromyalgia explains her symptoms. Tr. at 220. For the reasons outlined below, I agree with Dr. Low's assessment and find that Petitioner was correctly diagnosed with fibromyalgia by her treating rheumatologist, Dr. Nasseri.

a. Petitioner's Fibromyalgia Diagnosis is Supported by the Record

Ms. Dixon-Jones was diagnosed with fibromyalgia in 2006. Ex. 3 at 6. However, the records from this timeframe are unavailable. Petitioner's visit to Dr. Nasseri on February 14, 2013 references this fact, and notes that she has been a patient of the Arthritic & Rheumatic Clinic but has not been seen in several years. *Id.* During this visit in February of 2013, Petitioner was assessed as having "numerous tender points on trunk, and upper and lower extremities" as well as pain in her joints located at multiple sites. *Id.* at 7. Dr. Nasseri believed that "it [was] likely her symptoms which also include numerous trigger points on upper and lower extremities are a flare of her previously diagnosed fibromyalgia." *Id.*

On March 20, 2013, Ms. Dixon-Jones followed up with Dr. Nasseri complaining of "shoulder pain and burning sensation in her bilateral thighs." Ex. 3 at 1. She also stated that she has headaches in the occipital area on a daily basis. *Id.* Dr. Nasseri again noted "numerous tender points on trunk, and upper and lower extremities." *Id.* at 4. He reiterated his belief that her symptoms "are an exacerbation of her previously diagnosed fibromyalgia […] [and] that her fibromyalgia is very severe." *Id.*

Petitioner filed an article by Wolfe et al. entitled *The American College of Rheumatology Preliminary Diagnostic Criteria for Fibromyalgia and Measurement of Symptom Severity*. Ex. 71. In it, the authors state that a patient satisfies the diagnostic criteria for fibromyalgia if the following three conditions are met:

(1) Widespread pain index (WPI) ≥7 and symptom severity (SS) scale score ≥5 or WPI 3-6 and SS scale score ≥9.
(2) Symptoms have been present at a similar level for at least 3 months.
(3) The patient does not have a disorder that would otherwise explain the pain.

Ex. 71 at 8.

The WPI is calculated by adding one point for each area in which the patient has experienced pain over the past week. Because there are 19 possible areas of pain, a patient's WPI score will be between zero and 19.[51] *Id.* The SS scale score is calculated by first assigning points based on the severity of a patient's symptoms in three categories (fatigue, waking unrefreshed, and cognitive symptoms). A patient is assigned between zero and three points in each category for a maximum of nine points. *Id.* Then, between zero and three points are also assigned based on the severity of somatic symptoms.[52] *Id.* These two totals are added together and constitute the SS scale score, a number between zero and 12. *Id.*

Dr. Aradillas testified at hearing that the diagnostic criteria for fibromyalgia were developed in 2010. Tr. at 107-08. He makes the point that when Petitioner was first diagnosed with fibromyalgia in 2006, those criteria were not yet in use. He suggests that her 2006 diagnosis was made in error through the use of an outdated standard. In support of this opinion, Dr. Aradillas testified that Petitioner's medical records suggest that she had pain only in her arms, which was explained by carpal tunnel syndrome and radial nerve compression. *Id.* at 108.

There is not enough evidence to support or rebut the contention that Petitioner's 2006 fibromyalgia diagnosis was not in accordance with the 2010 diagnostic criteria, as the medical records pertaining to this diagnosis have not been filed. However, it is clear that when Dr. Nasseri evaluated Petitioner in February and March of 2013, the new and accepted criteria were in place, and that during these visits, Dr. Nasseri reaffirmed Petitioner's diagnosis of fibromyalgia.[53]

[51] The areas of pain include: left shoulder girdle, right shoulder girdle, left upper arm, right upper arm, left lower arm, right lower arm, left hip (buttock, trochanter), right hip (buttock, trochanter), left upper leg, right upper leg, left lower leg, right lower leg, left jaw, right jaw, chest, abdomen, upper back, lower back neck. Ex. 17 at 8.

[52] Possible somatic symptoms listed in the diagnostic criteria include: muscle pain, irritable bowel syndrome, fatigue/tiredness, thinking or remembering problem, muscle weakness, headache, pain/cramps in the abdomen, numbness/tingling, dizziness, insomnia, depression, constipation, pain in the upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, diarrhea, dry mouth, itching, wheezing, Raynaud's phenomenon, hives/welts, ringing in ears, vomiting, heartburn, oral ulcers, loss of/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, hearing difficulties, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms. Ex. 71 at 8.

[53] Dr. Aradillas did not discuss Petitioner's 2013 fibromyalgia diagnosis during his testimony at hearing.

After conducting a careful review of the medical records, I find that Dr. Nasseri's evaluation of Petitioner is thorough and appears to be consistent with fibromyalgia's diagnostic criteria. Because he is one of Petitioner's treating physicians, I give substantial weight and deference to Dr. Nasseri's opinion. I have no reason to question his diagnosis, especially when it is supported by Petitioner's own complaints, as documented in her contemporaneous medical records.[54] Further, there is no reason to believe that Dr. Nasseri, who is a rheumatologist, was unaware of the diagnostic criteria for fibromyalgia, or that he somehow incorrectly calculated the WPI or SS scale score or misapplied the diagnostic criteria in arriving at Petitioner's diagnosis.

Dr. Low credited Dr. Nasseri's examinations as "superb" and agreed that Petitioner's correct diagnosis is fibromyalgia. Tr. at 177. He enumerated several factors to support this opinion. Dr. Low testified that Petitioner's chronic fatigue, as well as the existence of numerous trigger points, identified and later injected by Dr. Nasseri, are both "very characteristic of fibromyalgia." *Id.* Dr. Low also discussed the waxing and waning nature of Petitioner's illness as being consistent with fibromyalgia and not with CRPS. *Id.* at 175. Further, Petitioner's medical records describe all over pain (as opposed to pain in a limb or impacting a region of her body). Dr. Low testified that "diffuse pain with trigger points is much more consistent with fibromyalgia than CRPS." *Id.* at 183.

I credit the opinions of Dr. Nasseri and Dr. Low over Dr. Aradillas. Petitioner was properly diagnosed with fibromyalgia, and she does not meet the diagnostic criteria for CRPS, which require no other diagnosis that better explains her signs and symptoms.

b. Petitioner Experienced Many Other Painful Conditions

In addition to fibromyalgia, Petitioner also experienced many other conditions, both painful and non-painful. A non-exhaustive list of these conditions includes: carpal tunnel syndrome, asthma, hypertension, hypothyroidism, pancreatitis, brachial plexopathy, gastroesophageal reflux disease, cholelithiasis, gastritis, uterine fibroids, chronic fatigue, chronic pain syndrome, ovarian cyst, disc herniation, lumbago, cervicalgia, myofascial pain syndrome, vertigo, cyclical vomiting

[54] Dr. Nasseri repeatedly referenced "numerous trigger points" in Petitioner's trunk and upper and lower extremities. Ex. 3 at 4, 7. The records from these rheumatology visits also list a number of the somatic symptoms enumerated in Ex. 71, to include: headaches (Ex. 3 at 1), depression (Ex. 3 at 2 under "past medical history"), rash (Ex. 3 at 6), insomnia (Ex. 3 at 7 under "past medical history"), tingling and numbness (Ex. 3 at 8 under "review of symptoms"), fatigue (Ex. 3 at 7 under "past medical history"), heartburn (Ex. 3 at 7 listed as "acid reflux" under "past medical history"), and wheezing (Ex. 3 at 7, asthma listed under "past medical history"). Because MiraLax is listed as a current medication (Ex. 3 at 1, under "current medications"), this also suggests that Petitioner suffers from constipation, another somatic symptom of fibromyalgia. In addition, Petitioner's medical records from close-in-time to these rheumatology visits also mention other somatic symptoms listed in Ex. 71. In September and November of 2012, Petitioner saw various doctors concerning thinking or remembering problems (*See* Ex. 10 at 21, September 17, 2012 visit to rule out Alzheimer's disease; Ex. 24 at 13, November 19, 2012 visit where doctor noted evidence of cognitive dysfunction). On February 19, 2013, Petitioner saw an optometrist and reported symptoms of ringing in ears (tinnitus), muscle aches, and blurred vision (Ex. 2 at 12-13). She sought treatment on March 3, 2013 for chest pain, abdominal pain, and purported seizures (Ex. 10 at 9). On September 13, 2012, Ms. Dixon Jones also complained of sleep difficulty and not feeling refreshed when she wakes (Ex. 24 at 10).

syndrome, memory loss, chest pain, insomnia, significant slowing in the posterior area of the cortex, recurrent rash, headaches, and bilateral shoulder adhesive capsulitis. Petitioner has also complained of seizures, PTSD after an epidural, PRES, brain swelling after flu vaccine, and sphincter of Oddi dysfunction. Petitioner's medical history, both before and after vaccination is extensive and complex. This involved medical history makes it difficult for Petitioner to establish that her pain was caused by vaccination, and further that no other diagnosis better explains her signs and symptoms.

Dr. Aradillas attempted to address this issue by attributing Petitioner's pain post-vaccination to the amplification of her pre-existing pain through the central sensitization process. Tr. at 128. I find Dr. Aradillas' explanation to be unpersuasive for the reasons discussed later in this decision.[55]

c. Petitioner's Medical Record Evidence Does Not Support a CRPS Diagnosis

(i) Petitioner did not have Regional Pain

As stated in the diagnostic criteria, CRPS is a disease that is typically regional in nature, impacting one or more limbs. "CRPS describes an array of painful conditions that are characterized by continuing regional pain that is seemingly disproportionate in time or degree to the usual course of any known trauma or other lesion." Ex. C at 1. In an article that he co-authored, Dr. Low writes that CRPS "is best considered a type of chronic limb pain with certain specific characteristics." Ex. F at 1. During the hearing, Dr. Low described regional pain as "outside of the distribution of one or two peripheral nerves. It's usually in a region of the body, such as an arm or a leg." Tr. at 171. In fact, numerous articles and case reports cited by Petitioner confirm

[55] Dr. Aradillas highlighted Petitioner's "new" pain radiating down to her right and left knees and her buttocks as "another example of how her old pains are starting to amplify because of the central sensitization process." Tr. at 130. As discussed *supra*, this is a mischaracterization of the medical record; Petitioner did, in fact have pain that radiated from her lower back into her legs in 2009.

this point.[56,57,58,59,60,61,62,63]

With respect to Petitioner, Dr. Aradillas testified that her initial sign and symptom of CRPS was facial pain, specifically pain around her ear. Tr. at 137-38. However, when asked to define Petitioner's region of pain, Dr. Aradillas testified as follows:

> **Q:** So what are – what is Ms. Dixon-Jones' region of pain at the onset of her CRPS?
>
> **A:** The – from what I read among the records, it was an exacerbation of her previous pains. The region of pain that it went to, it was her left buttock, right buttock, all the way down to knees – to the knees bilaterally.

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[56] Goebel A, et al. Intravenous Immunoglobulin Treatment of Complex Regional Pain Syndrome. ANN INTERN MED 2010; 152(3): 152-8 (filed as Ex. 49; hereinafter referred to as Ex. 49)(CRPS "is a painful, usually posttraumatic condition in a limb").

[57] Kohr D, et al. Autoimmunity against β_2 adrenergic receptor and muscarinic-2 receptor in complex regional pain syndrome. PAIN 2011; 152: 2690-2700 (filed as Ex. 50; hereinafter referred to as Ex. 50)("The main clinical features are pain and hyperalgesia, vasomotor, pseudomotor, and trophic changes in the affected limb").

[58] Blaes F, et al. Improvement of complex regional pain syndrome after plasmapheresis. EUR J PAIN 2015; 19: 503-7 (filed as Ex. 51; hereinafter referred to as Ex. 51)("Complex regional pain syndrome is a severe complication following trauma that is associated with vasomotor, sudomotor and sensory disturbances in an affected limb or region of the body").

[59] Goebel A, Blaes F. Complex regional pain syndrome, prototype of a novel kind of autoimmune disease. AUTOIMMUN REV 2013; 12: 682-6 (filed as Ex. 52; hereinafter referred to as Ex. 52)("Complex regional pain syndrome (CRPS) is a painful condition, which arises in a limb after trauma.

[60] Goebel A, et al. The passive transfer of immunoglobulin G serum antibodies from patients with longstanding Complex Regional Pain Syndrome. EUR J PAIN 2011; 15: 504.e1-504.e6 (filed as Ex. 61; hereinafter referred to as Ex. 61)("Complex regional pain syndrome (CRPS) is usually posttraumatic and restricted to one limb").

[61] Siegal SM, Lee JW, Oaklander AL. Needlestick Distal Nerve Injury in Rats Models Symptoms of Complex Regional Pain Syndrome. ANESTH ANALG 2007; 105(6): 1820-9 (filed as Ex. 68; hereinafter referred to as Ex. 68)("Complex regional pain syndrome (CRPS)-I consists of chronic limb pain.…").

[62] Jastaniah WA, et al. Complex regional pain syndrome after Hepatitis B vaccine. J PEDIATR 2003; 143: 802-4 (filed as Ex. 73; hereinafter referred to as Ex. 73)("Complex regional pain syndrome (CRPS) type I is a disorder of one or more extremities.…").

[63] *See also* Ex. 55 at 1 (CRPS "typically develops in an extremity after acute tissue trauma"); Ex. 56 at 1 ("Complex regional pain syndrome (CRPS) is a painful condition that develops after trauma to a limb"); Ex. 58 at 1 ("Complex regional pain syndrome type I (CRPS I) is a disorder of one or more extremities.…"); Ex. 60 at 1 ("Complex regional pain syndrome type I (CRPS I) is a clinical syndrome that affects one or more extremities.…"); Ex. 62 at 1 ("Complex regional pain syndrome type I (CRPS-I) is a complex clinical disorder of one or more extremities.…").

Q: So as I understand that criteria, the regional pain is where it starts, right, so the CRPS where you're going to have your first sign or symptom. So isn't it true, like, typically in CRPS someone will walk in and it's a limb and it's generally affected?

A: It is – that is true, yeah.

Q: Okay. So I'm asking you, what is the region of pain that her diagnosis started? And you're saying it was her left side, her left leg and buttock?

A: Left and right buttocks and left and right legs. It radiated – her pain radiated down there.

…

Q: So you think facial pain is a first symptom, but her region of pain, according to the Budapest criteria, is her left and right legs?

A: Yes.

Tr. at 142-44. As noted *supra*, the medical literature consistently describes CRPS as a regional disorder impacting one or more limbs. Dr. Aradillas' description of Petitioner's initial symptom of CRPS as facial pain, while relating her region of pain was her left and right buttocks and left and right legs, is not consistent with the description of CRPS cited in much of Petitioner's medical literature.

As evidenced throughout her post-October 6, 2011 flu vaccination medical records, Petitioner's pain was not regional in nature impacting one or more limbs. Instead, Petitioner's pain is best characterized as diffuse and/or widespread impacting different parts of her body. Sometimes this included pain to the extremities, but often it did not. Petitioner complained of ear pain (Ex. 26 at 26, 27; Ex. 20 at 4) which also radiated into her left jaw (Ex. 12 at 24), abdominal pain to include pain in the right and left upper quadrant (Ex. 11 at 8; Ex. 12 at 26; Ex. 12 at 37; Ex. 16 at 23; Ex. 16 at 29; Ex. 16 at 36; Ex. 10 at 192), low back pain that radiated into her right buttock, left buttock, right knee, and left knee (Ex. 16 at 23; Ex. 16 at 29; Ex. 16 at 34; Ex. 16 at 91; Ex. 33 at 3), mid-back pain (Ex. 16 at 29; Ex. 16 at 36; Ex. 33 at 3), pain in her feet and legs (Ex. 16 at 29; Ex. 16 at 34; Ex. 16 at 91; Ex. 120 at 36), a generalized constant burning sensation that migrated to different areas of her body (Ex. 27 at 32), arm pain (Ex. 26 at 27; Ex. 18 at 3; Ex. 24 at 9; Ex. 120 at 5), tingling and piercing sensation in random areas (Ex. 16 at 49), generalized myalgias in the upper extremities (Ex. 24 at 2), shoulder pain (Ex. 3 at 6; Ex. 3 at 1; Ex. 16 at 91; Ex. 127 at 32; Ex. 17 at 13), thigh pain (Ex. 3 at 6; Ex. 3 at 1), hip pain (Ex. 16 at 91), and hand pain (Ex. 127 at 32; Ex. 127 at 15).

As Dr. Low discussed in his testimony, this type of widespread migratory pain is not characteristic of CRPS but is consistent with fibromyalgia. *See* Tr. at 183.

(ii) Petitioner did not Experience Unrelenting, Persistent Pain and/or Other Symptoms

Dr. Low described the pain associated with CRPS during his testimony, stating that it "is unrelenting, simply doesn't change. It doesn't change from day to day. The patient isn't going to come in and see one physician and have a normal exam and the next day have severe abnormalities as noted by someone else." Tr. at 171-72. Dr. Low clarified that in addition to the pain associated with CRPS, the other signs such as skin color changes and edema also do not fluctuate. *Id.* at 218-19. He further testified as follows:

> **Q:** Does the pain in the initial region subside with CRPS?
>
> **A:** It doesn't change very much from day to day, and it never goes away unless the condition improves.
>
> **Q:** Is there a waxing and waning course to CRPS?
>
> **A:** Not – not typically, unlike, say, fibromyalgia, where they get periods of improvement and periods of worsening. With CRPS, you don't. If one physician sees it, the next physician should see it.

Tr. at 175. In fact, the medical literature filed in this case supports this concept. In an article by Alexander et al., the authors state, "[t]he pain in CRPS is continuous, it worsens over time…" *See* Ex. 43. Schwartzman et al. studied the evolution of CRPS signs and symptoms. *See* Ex. 41. Dr. Low referred to this article in support of his testimony regarding the unrelenting nature of CRPS pain. Specifically, he highlighted figure 2:

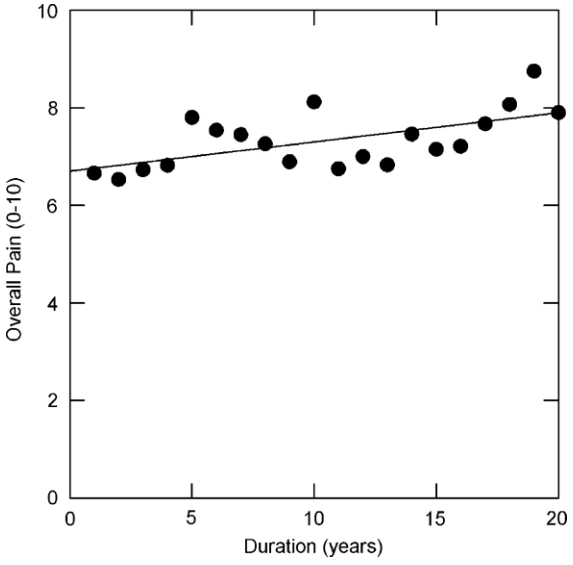

FIGURE 2. Variations in the intensity of overall pain on a 0 to 10 numerical rating scale versus duration of disease. The intensity of overall pain demonstrated a statistically significant positive correlation with progression of disease ($r = 0.60$, $P = 0.005$).

Ex. 41 at 3. Dr. Low testified that figure 2 demonstrates CRPS patients have severe pain, the pain increases over time, and the pain is unrelenting "and does not change from moment to moment."

Tr. at 199-200. Dr. Aradillas also agreed that the pain associated with CRPS is not intermittent. *Id.* at 96, 100-01.

Dr. Aradillas testified that the start of Petitioner's CRPS was her left ear pain. "The pain was piercing, worse if she touches anywhere around the ear, so that is definitely what you would call allodynia, a nonpainful stimulus, just touch is perceived as painful. So that tells me that at that time, the central sensitization process was starting … to happen." Tr. at 126.

Petitioner reported ear pain at medical visits on October 12, 2011 (Ex. 26 at 27), October 26, 2011 (Ex. 26 at 26), and November 2, 2011 (Ex. 12 at 24). During her November 4, 2011 medical appointment with Dr. Schneyer, Petitioner reported ear pain since receiving her flu shot. She stated that "[i]t occurred intermittently every few days up to last Friday. Since then she has not had any piercing ear pain. She is taking Dilaudid for pain, but she thinks the pain just dissipates on its own." Ex. 20 at 4. Petitioner's ear pain, described by Dr. Aradillas as indicating the start of the central sensitization process, went away in early November 2011. This is not consistent with Dr. Low's description of pain associated with CRPS.

Petitioner has also experienced abdominal pain since at least 2003. During his testimony, Dr. Aradillas discussed Petitioner's burning, band-like abdominal pain as indicative of CRPS. On July 21, 2014, Petitioner followed up with Dr. Pasricha for her symptoms of chronic nausea, GERD, and left upper quadrant abdominal pain. Ex. 14 at 7. During this visit, Petitioner experienced no epigastric pain, and her abdominal pain was described as "intermittent" and "mainly post-prandial and crampy in nature." *Id.* at 7, 12. This type of intermittent pain is not consistent with Dr. Low's description of pain associated with CRPS.

At various medical visits, Petitioner has described her pain as both migratory and at times, intermittent. For example, on February 17, 2012, Petitioner complained that she was having "diffuse pain throughout her entire body from her fibromyalgia." Ex. 18 at 7. On April 18, 2012, Petitioner stated that her pain was a "constant burning sensation that migrates to different areas of her body." Ex. 27 at 32. On May 7, 2012 she reported "tingling and piercing sensation in random areas." Ex. 16 at 49. On February 14, 2013, Petitioner described "intermittent burning pain in her bilateral shoulders, thighs, or knees." Ex. 3 at 6. Dr. Low opined that these various descriptions are common symptoms seen in fibromyalgia and are not characteristic of CRPS. *See* Tr. at 171-72, 175, 183.

In addition to CRPS pain being characterized as unrelenting, Dr. Low also described the other signs of the disease, such as swelling and redness as remaining constant. *See* Tr. at 218-19.

On June 17, 2013, Petitioner visited Dr. Williams complaining of bilateral upper extremity pain and weakness. Dr. Williams noted upon inspection of her left and right upper extremities that there was "no erythema, induration, swelling, warmth, mass or scars normal appearance and normal bulk and tone with no wasting." Ex. 127 at 32. "Vascular right" and "vascular left" both state, "normal color and temperature". *Id.* at 33. Petitioner followed up with Dr. Williams on September 30, 2013, March 31, 2014, May 27, 2014, and August 21, 2014. (*See* Ex. 127 at 29, 25-26, 22, 18). Each time, Dr. Williams made consistent annotations regarding redness, swelling, warmth, color, and temperature. In fact, the annotations are identical, except that the visits on

March 31, 2014, May 27, 2014, and August 21, 2014 under inspection left and inspection right state "no erythema, induration, swelling, warmth, or mass" whereas on June 17, 2013 and September 30, 2013, they state, "no erythema, induration, swelling, warmth, mass or scars normal appearance and normal bulk and tone with no wasting." The vascular annotations are identical.

Petitioner visited Dr. Aradillas on October 13, 2014. Dr. Aradillas noted "[e]rythema of the shoulders and supraclavicular fossa, there was also swelling specially [sic] at the right arm throughout but evident at the hand and forearm along with a purplish discoloration of both hands." Ex. 23 at 7.

On December 4, 2014, Petitioner followed up with Dr. Williams. Dr. Williams again noted in the inspection of her right and left extremities "no erythema, induration, swelling, warmth, or mass." Ex. 127 at 14. He also noted (as in each of his previous examinations) under "vascular right" and "vascular left" that Petitioner had "normal color and temperature". *Id.* Dr. Williams performed similar examinations on March 16, 2015 and July 13, 2015 with identical findings. *See* Ex. 127 at 9-10, 5.

Petitioner had no swelling or color changes during any of her visits with Dr. Williams, which occurred both before and after her visit with Dr. Aradillas. The apparent change in Petitioner's color and swelling of her upper extremities are not consistent with CRPS as described by Dr. Low.

(iii) Petitioner's Bone Scan Results do not Support a CRPS Diagnosis

Dr. Low testified about the three-phase bone scan as a helpful test in either including or excluding CRPS as a diagnosis. *See* Tr. at 192-94. While a negative test does not eliminate the possibility that the patient has CRPS, it reduces the likelihood of CRPS if the test is normal. *Id.* at 194. In an epidemiologic study that he supervised, Dr. Low and the authors reviewed a group of patients who had been diagnosed with CRPS. In that study, a subset of those patients had a three-phase bone scan. Approximately 85 percent of those tested had an abnormal scan, which "showed a pattern consistent with the diagnosis of CRPS." Ex. F at 3. A similar percent also had abnormal autonomic function tests. *See* Ex. F; Tr. at 192. Dr. Low went on to testify regarding bone scan testing that "[i]f you looked at all the data, it had a sensitivity and a specificity[64] of over 80 percent. Tr. at 193.

Dr. Nasseri, Petitioner's treating rheumatologist, ordered a whole-body bone scan to evaluate Petitioner for CRPS. Ex. 11 at 41. The results of the examination concluded that Petitioner had "[n]o scintigraphic evidence of reflex sympathetic dystrophy." *Id.*

The negative results of Petitioner's bone scan do not completely exclude a CRPS diagnosis. However, they provide solid and objective support for Dr. Low's opinion that Petitioner did not have CRPS.

[64] Sensitivity reflects "the conditional probability that a person having a disease will be correctly identified by a clinical test." Dorland's at 1692. Specificity reflects "the conditional probability that a person not having a disease will be correctly identified by a clinical test." *Id.* at 1742.

d. The Opinions of Petitioner's Treating Physicians

Several of Petitioner's treating doctors attributed her condition to her flu vaccination while many others did not. Treating physicians are often entitled to deference because, having evaluated their patient, they are able to determine whether "a logical sequence of cause and effect shows that the vaccination was the reason for the injury." *Capizzano*, 440 F.3d at 1326. In this case, the opinions of treating physicians can be divided into several categories: 1) physicians who directly attribute Petitioner's symptoms to her flu vaccination; 2) physicians who recite the history provided by Petitioner; and 3) physicians who do not attribute Petitioner's symptoms to her flu vaccination.

(i) Physicians who Attribute Petitioner's Condition to her Vaccination

Shortly after her vaccination, Petitioner experienced what she described as an allergic reaction. At least one of her treating physicians commented on this reaction and linked it to her recent flu vaccination. On October 12, 2011, Petitioner presented to her allergist, Dr. Mardiney, who noted that, "last Thursday she had a flu vaccine administered at work. The injection was given about 11:30 A.M. and at about 2 o'clock the right arm swelled. It stayed painful, but at 3:30 A.M. on Friday morning she woke up with extreme pain in the left ear, swelling of both hands, facial rash and shortness of breath." Ex. 26 at 27. By the time Petitioner presented to Dr. Mardiney, she did not have any signs of allergic reaction. *See Id.* Dr. Mardiney diagnosed Petitioner with "adverse response to flu vaccine, manifested by angioedema, as well as bronchospasm, Eustachian tube dysfunction and skin rash." *Id.* Other treating physicians have noted Petitioner's allergic reaction in subsequent records.

While several of Petitioner's treating physicians diagnose her with an allergic reaction to the flu vaccine, Petitioner has alleged that the flu vaccine caused her to develop CRPS. As discussed in more detail below, I do not find Petitioner's theory, that an allergic reaction led to the production of proinflammatory cytokines which in turn initiated the central sensitization process and caused her to develop CRPS, to be supported by preponderant evidence. As a result, the opinions of treating physicians who ascribe Petitioner's allergic reaction to her flu vaccination do not alter my analysis in this case.

Other than Dr. Aradillas, the other treating physician who attributed Petitioner's condition to her flu vaccination is Dr. Kozachuk. Dr. Kozachuk, on the first day he treated Ms. Dixon-Jones, found that her "physical symptoms of chronic pain and cognitive dysfunction show direct causation to the accident of 10-6-11, and [that she] is totally and temporarily disabled." Ex. 24 at 3-4. It is unclear how Dr. Kozechuk arrived at this conclusion, as he did not elaborate on his basis for connection of the flu vaccine with Ms. Dixon-Jones' symptoms. Dr. Kozachuk's statements regarding diagnosis are conclusory and do not appear to be supported by the medical records. Accordingly, I do not find his assertions regarding the causality of the flu vaccine to be persuasive.

As discussed earlier in this decision, Dr. Kozachuk was reprimanded by the Maryland Medical Board and placed on probation for selling controlled substances in exchange for cash in public places. His behavior was described by the Board as "a flagrant abandonment of

professionalism." Although I did not base my evaluation of Dr. Kozachuk's diagnosis on this incident, the Board's finding did not serve to buttress his opinion in this case.

(ii) Physicians who Recite the History Provided by Petitioner

Petitioner's records are replete with mention of her many prior conditions. For example, PA Elisha Locke noted that Petitioner "has a history of CRPS in the left arm. She reported that the symptoms in the left arm began after an influenza injection which later reportedly developed CRPS." Ex. 120 at 10. In this record, it appears that Petitioner provided PA Locke with a history, and that history was entered into the record. As an additional example, the records from Dr. Kramer (psychologist) listed Petitioner's "problems/diagnoses" as "late effect of adverse effect of drug, medicinal, or biological substance." Ex. 27 at 30. Again, because Dr. Kramer is a psychologist, it appears that he entered Petitioner's history under the "problems/diagnoses" section of the record. While I have considered the many records that contain this type of reference, because they involve a recitation of medical history provided by Petitioner as opposed to a separate assessment, they do not alter my analysis in this case.

(iii) Physicians who do not Attribute Petitioner's Condition to her Vaccination

A number of Petitioner's treating physicians specifically commented on the flu shot and declined to provide a link between the vaccination and her symptoms. For example, Petitioner visited Dr. Schneyer on November 11, 2011 with complaints of imbalance and dizziness. In discussing the vaccination, Dr. Schneyer stated, "I explained to Mrs. Dixon-Jones that I did not know what is causing her symptoms or why they started after her flow [sic] shot. However, her inner ear seems to be functioning normally with a normal audiogram and ENG." Ex. 20 at 2.

Similarly, on December 19, 2011, Dr. Sellman noted that "it is speculative what event occurred this fall to cause Mrs. Dixon Jones to intermittently have problems with memory loss as well as vision and balance." Ex. 18 at 16. In a later record, on April 26, 2012 Dr. Sellman stated, "I spoke at great length today to Mrs. Dixon Jones and her husband, Melvin. I explained that I have no experience in her specific allegations that she is having problems as a complication of the flu shot." *Id.* at 3. In context, this comment certainly does not attribute Petitioner's symptoms to her vaccination.[65]

Importantly, except for Dr. Aradillas, none of Petitioner's treating physicians diagnosed her with CRPS. I have considered all the medical records in this case, to include statements by Petitioner's treating physicians in arriving at my determination.

[65] On March 14, 2012, Petitioner visited Dr. Sellman for evaluation of impaired memory which she indicated was caused by her flu vaccination. In the notes from this visit, Dr. Sellman remarks upon an inconsistency in Petitioner's behavior. He writes, "She seems to be awake, alert, and responsive. She was quite adamant on recent details with respect to days, dates, and times that she has called my office to verify that I had her records. At the same time, she then explained to me that her memory was very poor with respect to recent and long-term events." Ex. 18 at 5-6.

The Federal Circuit held in *Broekelschen*, 618 F.3d at 1346, that determining "causation turns on which injury [petitioner] suffered." The issue in that case was whether flu vaccine caused Dr. Broekelschen transverse myelitis or anterior spinal artery syndrome. *Id.* at 1342. The special master found respondent's neurologic expert more credible than Petitioner's expert, and thus dismissed the case. Petitioner appealed on the basis that the special master first had to determine if petitioner made a prima facie case of causation in fact and, only then, decide if respondent's known factor unrelated (anterior spinal artery syndrome) was the cause in fact of petitioner's condition. The Federal Circuit disagreed, stating "nearly all the evidence on causation was dependent on the diagnosis of Dr. Broekelschen's injury." *Id.* at 1346.

Based on the totality of the record, I find that Petitioner's fibromyalgia diagnosis is supported by the record, and her medical record evidence does not support a CRPS diagnosis. In arriving at this determination, I have weighed the testimony of Dr. Low and Dr. Nasseri over that of Dr. Aradillas and Dr. Kozachuk. I find there is not preponderant evidence that Petitioner has CRPS.

D. *Althen* Prongs

Because Petitioner has not established that she had CRPS, further analysis is unnecessary. However, for the sake of completeness, I will briefly analyze the *Althen* prongs.

1. *Althen* Prong 1: There is not Preponderant Evidence that the Flu Vaccine Can Cause CRPS in the manner alleged by Petitioner in this case

As described by extensive literature and confirmed by both experts, the exact mechanism for onset of CRPS is yet unknown. Generally, CRPS can develop after a surgery, traumatic event, or even a non-traumatic minor injury. Dr. Low testified that CRPS following needle stick, for example, has been documented in literature. Tr. at 195.

Petitioner's theory of causation was multifaceted. Petitioner's expert posited that Petitioner's CRPS developed not by needle stick, but rather from an inflammatory response following her flu vaccination. According to Dr. Aradillas,

> the flu vaccine caused the normal activation of the innate system, causing increasing inflammatory cytokines to circulate, plus the vaccine also caused an allergic reaction, causing the degranulation of mast cells, which both together caused the permanent activation of microglia and astrocytes, glial cells surrounding the synapse of the pain transmission neurons, which led to this permanent glutamate-dependent neuroplasticity or central sensitization syndrome and manifested clinically as a worsening of her or amplified her old pains and the development of complex regional pain syndrome.

Tr. at 131. In support of this theory of causation, Petitioner presented several articles that explore the involvement of inflammatory processes and mast-cell mediation as possible mechanisms involved in CRPS.

Petitioner's theory of causation, however, was not supported by the literature. First, though there is evidence to suggest that pro-inflammatory cytokines likely play a role in CRPS (although it is not clear what that role is), heightened cytokine levels are not thought to be the initiating factor for the development of CRPS. Instead, cytokine expression is part of the inflammatory component[66] of the acute phase of CRPS, which is triggered by tissue trauma or neuronal injury. Ex. 82 at 3. In fact, literature stated that while the involvement of heightened cytokine expression had been noted in patients already exhibiting CRPS, especially in the acute phase, "to date, no human studies have directly evaluated the role of inflammatory factors in the onset of CRPS." Ex. 55 at 6. Furthermore, it is continuously suggested that inflammation could be but one of many mechanisms that, combined, "play a role in the pathophysiology of CRPS,"[67] and that "local rather than systemic inflammatory responses appear to be relevant in CRPS." *See* Ex. 74 at 2. Therefore, while the theory involving heightened cytokines in the initiation of CRPS may merit further research, the state of literature at this time does not suggest that the systemic immune response involved in vaccination can trigger nerve damage or neuronal injury and the subsequent complex central sensitization process that eventually leads to CRPS.

In addition to the above, I note special masters have found that general cytokine-based theories of causation are not persuasive. *Zumwalt on behalf of L.Z. v. Sec'y of Health & Human Servs*., No. 16-994V, 2019 WL 1953739, at *18 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (noting that "[t]he fact that vaccines are known to stimulate cytokine production . . . does not amount to a reliable causation theory that such stimulation is necessarily disease-causing"); *Inamdar v. Sec'y of Health & Human Servs*., No. No. 15-1173V, 2019 WL 1160341, at *17 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (noting that the proposition that vaccines can cause diseases by "induc[ing] the production of proinflammatory cytokines . . . has several deficiencies"); *McCabe v. Sec'y of Health & Human Servs*., No. 13-570V, 2018 WL 3029175, at *47-55 (Fed. Cl. Spec. Mstr. May 17, 2018); *McGuire v. Sec'y of Health & Human Servs*., No. 10-609V, 2015 WL 6150598 at *12-18 (Fed. Cl. Spec. Mstr. Sep. 18, 2015) (noting that the petitioner had failed to introduce "persuasive evidence to rebut the IOM's conclusion that no evidence supports a conclusion that cytokines cause a disease").

Second, Petitioner's presentation of literature exploring an involvement of mast cells does not indicate that mast cells are involved in the development of CRPS. Rather, literature presented supports the involvement of mast cells "in the pathophysiology of inflammation in CRPS,"

[66] Literature filed by Petitioner suggests that chronic regional and neurogenic inflammation may be key components in the initiation of CRPS. *See* Goh EL, Chidambaram S, Ma D. Complex regional pain syndrome: a recent update. BURNS TRAUMA 2017; 5:2 (filed as Ex. 82; hereinafter referred to as Ex. 82). This theory led to the use of anti-cancer drugs, lenalidomide and thalidomide, in CRPS pain treatment. *Id*. at 6. Though treatment efforts showed initial promise, phase IIb trial of lenalidomide failed "to show any benefit over the placebo." *Id*. Still, the exploration of immunomodulatory treatments and the role of neurogenic inflammation as an initiating event of CRPS fails to provide support for the flu vaccine's ability to trigger chronic regional or neurogenic inflammation.

[67] Dirckx M, et al. Mast Cells: A New Target in the Treatment of Complex Regional Pain Syndrome? PAIN PRACT 2013; 13(8): 599-603 (filed as Ex. 74; hereinafter referred to as Ex. 74).

specifically, in the acute phase.[68] Ex. 74 at 1; *see also* 76 at 7. As such, mast cells are believed to be involved as part of the ongoing inflammatory components of numerous neurodegenerative diseases. *See* Ex. 74. Though the role of mast cells in the manifestation of pain and inflammation has been documented, mast cell expression triggered by allergic reaction has not been identified as a mechanism by which chemical stimulation of nociceptors resembles the tissue damage or nerve injury involved in the initiation of CRPS. Thus, mast cell involvement has not been recognized as a causative factor for CRPS. *See generally* Ex. 76.

Finally, Petitioner has not demonstrated that the flu vaccination, combined with a subsequent allergic reaction, can cause a reaction such that specific targeting of nociception can occur. Consequently, Petitioner cannot illustrate through literature that such a localized reaction can mirror that of a noxious or traumatic event, one that leads to the repetitive stimulation of nerve endings as a result of tissue damage or nerve injury and contributes to the central sensitization process.

Accordingly, I do not find that Petitioner has met her burden in providing a theory of causation linking the flu vaccination to CRPS. The literature does not support the development of CRPS following an inflammatory or allergic event incited by vaccination, but rather suggests only that components of inflammatory processes are involved in the expression CRPS and its numerous symptoms.

2. *Althen* Prong 2: There is not Preponderant Evidence that the Flu Vaccine Did Cause CRPS in Petitioner's Case

As discussed above, Petitioner did not meet her burden in providing evidence that vaccination did cause her CRPS because I find that 1) Petitioner cannot establish that she has CRPS, and 2) Petitioner cannot establish that flu vaccination can cause CRPS.

First, in order to prove that the vaccination Petitioner received on October 6, 2011 caused CRPS, Petitioner must establish that she has CRPS, which in this case she failed so to do. Petitioner was not able to show that her post-vaccination symptom presentation met the diagnostic criteria for CRPS, was labeled as CRPS by her treating physicians, or was not better explained by a diagnosis of fibromyalgia. For example, Petitioner's pain was not regional in nature but rather diffuse, spread throughout her entire body. Similarly, Petitioner did not present with the unrelenting pain characteristic of CRPS. Petitioner's pain symptoms waxed and waned in both duration and presentation. In particular, Petitioner presented to Dr. Aradillas in October 2014 with erythema of the shoulders, swelling of the right arm, and discoloration of both hands, signs which contributed to his diagnosis of CRPS. However, at eight appointments with Dr. Williams, both before and after October 2014, the visit records indicate that Petitioner did not exhibit these signs. Both experts confirmed that intermittent presentation of signs and symptoms was uncharacteristic of CRPS.

[68] Aich A, Afrin LB, Gupta K. Mast Cell-Mediated Mechanisms of Nociception. INT J MOL SCI 2015; 16: 29069-92 (filed as Ex. 76; hereinafter referred to as Ex. 76).

As I stated above, I find that Petitioner's signs and symptoms were better explained by a diagnosis of fibromyalgia. Petitioner's widespread pain, waxing and waning symptoms, and ongoing presentation of numerous somatic symptoms were described as characteristic of fibromyalgia. Further, I find that Dr. Nasseri's examination leading to Petitioner's diagnosis was thorough and in keeping with the current diagnostic standard.

In addition to failing to establish that she had CRPS, Petitioner also failed to establish that the flu vaccination can cause CRPS. Petitioner's theory of causation was based on the general process behind central sensitization, observed in many neuropathies. Petitioner was not able to demonstrate that this process could be triggered or altered by a flu vaccination or an allergic reaction to a flu vaccination. Even so, several factors anchoring Petitioner's own theory were not present in Petitioner's medical testing.

First, Petitioner's theory relied on heightened cytokine response to the vaccination and during the alleged reaction to the vaccination. Petitioner presented literature discussing the pathophysiologic mechanisms of CRPS and the role that cytokine expression may serve, as one of the multiple mechanisms usually involved. Ex. 55 at 2. Clinical trials have indicated that corticosteroids can be effective in significantly improving the symptoms of acute CRPS, "suggesting the possibility that inflammatory mechanisms might contribute to CRPS, at least in the acute phase." *Id*. at 5. Such an inflammatory mechanism could occur in either of two ways, by means of classic inflammatory response through the actions of immune cells after tissue trauma or by neurogenic inflammation. Both mechanisms would result in an increase in proinflammatory cytokines secreted. Notably, the local blister fluid, circulating plasma, and cerebrospinal fluid ("CSF") of CRPS patients in some studies exhibited significantly elevated levels of TNF-α, interleukin-1β, -2, and -6.

Petitioner's medical records, however, indicated that Petitioner's proinflammatory cytokines, specifically TNF-α and IL-1β, were not significantly elevated at the levels observed in CRPS patients. On October 16, 2014, Petitioner's CSF was tested for cytokine expression. Ex. 23 at 22. Petitioner's IL-1β was measured at 1.6 pg/mL, with a reference factor of less than 1.0 pg/mL. *Id*. Though slightly above the reference factor indicated, I do not find this increase to be significant in light of the increased levels of IL-1β recorded in CRPS patients studied.[69,70] Petitioner's TNF-α was measured at 1.7 pg/mL, within the reference factor of 1.2 – 15.3 pg/mL. Ex. 23 at 10. Thus, I do not view Petitioner's TNF-α or IL-1β levels to be indicators of CRPS.

Second, Petitioner's theory depends on a heightened mast cell response triggered by an allergic reaction to the vaccination. There was no indication in Petitioner's medical records of any irregularly heightened mast cell expression. Though an allergic reaction was noted by Dr. Mardiney, Dr. Mardiney did not observe any signs of the reaction during the appointment and,

[69] Alexander GM, et al. Changes in Plasma Cytokines and Their Soluble Receptors in Complex Regional Pain Syndrome. J Pain 2012; 13(1): 10-20 (filed as Ex. 78, hereinafter referred to as Ex. 78).

[70] In one such study, cluster analysis revealed that in a subgroup of patients, "the increase in … IL-1β [is] related to the pathophysiology of the disease." Ex. 78 at 8. In comparison to 2.16 pg/mL in control patients, increases of plasma cytokines to 2.47 and 3.17 pg/mL in CRPS patients were not considered significantly different from controls. *Id*. at 7.

therefore, did not find it severe enough to request further diagnostic testing. As such, no ongoing mast cell expression was recorded. Even if Petitioner had suffered from an allergic reaction, triggering a typical mast cell response, there is no clear indication in the medical records that this response did not resolve or that it led to the development of nerve injury.

Therefore, even if Petitioner's theory of causation were viable under a more likely than not standard, Petitioner's diagnostic testing did not support the existence of the underlying factors necessary for Petitioner's purported causative process to occur. There is not preponderant evidence that the flu vaccination did cause CRPS in Petitioner's case.

3. *Althen* Prong 3: One Month Post Vaccination Is a Medically-Appropriate Onset Interval

As discussed extensively above, I do not find that Petitioner has CRPS. It is within this framework that I analyze whether the onset of her CRPS occurred within a medically feasible time frame.

Accounting for Petitioner's assertion of onset, Dr. Aradillas initially stated that Petitioner's first presentation of CRPS was likely her ear pain, one month following vaccination. However, Petitioner's ear pain had resolved by November 4, 2011, making this symptom inconsistent with a CRPS diagnosis. *See supra*. Ex. 20 at 4. If Petitioner's ear pain were a presentation of CRPS, according to Dr. Low, the onset would have occurred within a medically feasible time frame.[71] However, CRPS is characterized by a presentation of regional pain. When questioned about Petitioner's region of pain at the onset of her CRPS, Dr. Aradillas testified that Petitioner's region of pain was her left and right buttocks, extending bilaterally to her thighs and knees. If this were instead Petitioner's initial presentation of pain, then onset is difficult to determine, since Petitioner exhibited similar symptoms prior to vaccination. After vaccination, Petitioner did not seek treatment for such pain until December 9, 2011, about two months after she received her flu shot.

Assuming for the sake of this analysis that Petitioner had CRPS, and the onset of her disease began with ear pain approximately one month after vaccination, I find that Petitioner provided preponderant evidence in support of *Althen* prong 3.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, tests, and reports, as well as the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. Petitioner has failed to offer credible evidence showing that she suffered from CRPS, and she has failed to show that the vaccination she received caused any of her complaints. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[72]

[71] Dr. Low testified that the condition would "develop rapidly, certainly within two months, probably within a month." Tr. at 194.

[72] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master